Challenges & Change

Reports from the Veterans Health Administration (VHA) Bioethics Committee

1999

1. Futility Guidelines: A Resource for Decisions about Withholding and Withdrawing Treatment

Purpose

This paper will serve as a resource for discussions of the concept of futility from the VA perspective. It is hoped that this discussion will lead to a proposal for departmental guidelines, to a formulation of a national VA position or definition, and where appropriate to institutional policies within VA facilities compatible with their patient population mix and their complexity, mission, community, educational affiliation, and staff culture.

Background

American medicine has been struggling with the issue of "futility" under a number of guises for at least ten years. With the ever-present emphasis on "informed consent," patients and surrogates perceived correctly that they could accept or refuse the therapy offered to them. As they became more medically knowledgeable and sophisticated, they began to ask for treatments that their physicians considered not medically indicated, totally inappropriate, or having little chance of success or benefit. In some cases patients and surrogates refused to permit withdrawal of treatment that the physicians felt was not achieving any medical benefit and often was very resource intensive. At the same time, the technological explosion provided the means to support physiologic functions and to treat what had previously been

fatal conditions. However, not all outcomes were considered successful and many patients remained comatose, on life-support, or in persistent vegetative state (PVS).

Physicians used the term "futile" to try to convey to patients and surrogates that offering or continuing treatment was, in their opinion, pointless, worthless, or unlikely to produce positive results or any benefit. Unfortunately, rather than enhance communication, the term can establish a barrier with its implications of finality and hopelessness. Some patients and surrogates began to feel that their values, concerns, and concepts of quality-of-life were being overlooked, bypassed, or forgotten and that their perception of the value of even a limited quality of life or of limited percentage of success of a particular treatment was not being considered appropriately.

The debate about the meaning of futility continued, fueled by other developments of concern:

1. the exponential rise in health care costs;
2. the continued growth in development and diffusion of high-technology and the resulting question of whether the effects produced in its use (or overuse) provided benefit to patients;
3. the accelerated aging of society and the observation that the elderly and the dying appear to be the heaviest users of health services;
4. the new emphasis on outcomes research;
5. the desire to place some limitations or restrictions on patient autonomy and to focus more on concepts of justice in allocation of scarce resources;
6. evidence of continued paternalism and physician domination or physician autonomy;
7. fuzziness in the attempts at definition of the term "futility;"
8. capricious judgments involving the "social worth" of particular patients; and

9. little or no distinction of the components of judgments of futility, e.g., clinical criteria, appropriate decision makers, required communication, and documentation.

Recent Definitions

It appears that in the past the term "futility" has most often been used in individual cases, on a one-on-one basis at the bedside, where the physician felt it necessary or appropriate not to discuss, not to offer, to withhold, to withdraw, or to deny a particular therapy for one or more reasons. This plan could occur even though the patient or surrogate had requested the therapy or asked that it be continued. The "reasons" included, but were not limited to:

- totally inappropriate;
- never tried before;
- previously tried but rarely or never successful;
- previously tried but not successful in category into which patient falls;
- previously tried but unsuccessful in last 100 cases (statistical or quantitative futility);
- would produce a physiologic effect but no benefit to patient;
- benefits produced would be significantly outweighed by physical or physiologic burdens necessitated;
- results of treatment would produce negative quality of life, only preserve permanent unconsciousness, or fail to end total dependence on the Intensive Care Unit (qualitative futility); and
- benefits produced would not be worth the economic burden (non-"costworthy" or economic futility).

Much of the foregoing rationale is based upon physician decisions or physician values. It is argued that this trend is a return to paternalism or subversion of patient autonomy, to the exclusion of patients values.

The literature reveals a developing consensus that emphasizes the patient's goals and value system as critical elements in any discussion of futility. The importance of communication between physician and patient or surrogate cannot be stressed too strongly. The physician must ask about and be aware of the patient's religion, culture, family circumstances, and values and must communicate and be assured that patient or surrogate understand the diagnosis and prognosis. These elements should be factored into any judgment about "futility," or the patient or surrogate may feel isolated and alienated at a time when they may be in greatest need of support and understanding. However, some feel that acknowledging patients' goals and wishes will lead to demands for pointless or inappropriate care despite no reasonable, realistic likelihood of success or benefit. They express this concern while acknowledging the challenges of determining what is "reasonable" and determining who decides.

Do We Need to Define Futility?

It has been suggested that futile treatment be defined as that which affords no benefit or marginal benefit, weighing the intrusiveness, burdens, and risk against the ultimate outcome.

However, since the term "futility" in the clinical sense usually arises in a context of withholding or withdrawing a particular modality, and since the term has become volatile, almost inflammatory, it may be more appropriate to define those situations where diagnostic/therapeutic modalities will be withheld or withdrawn.

It is also suggested that the term "futile treatment" be used, since care is never futile.

Withholding and Withdrawing of Treatment: Refusals and Futility Assessments

A. Treatment may be withheld or withdrawn following refusals when:

   1. a competent patient refuses the treatment after having received relevant information;

2. an incompetent patient's surrogate refuses, in compliance with a valid Durable Power of Attorney for Health Care; or

3. an incompetent patient's surrogate refuses, in compliance with patient's wishes (substituted judgment) or best interest after weighing burdens and benefits.

B. Treatment may be withheld or withdrawn on the basis of futility assessments when:

1. treatment would only serve to prolong the dying process and bring no relief of a patient's suffering (death is inevitable and imminent and treatment includes artificial feeding and hydration where the patient is only being maintained in his/her current state with no hope of improvement);*

2. treatment would only maintain permanent vegetative state (PVS) once that diagnosis had been made and its irreversibility had been confirmed;**

3. continued treatment is in violation of an established medical center policy (see #2 under Guiding Principles);**

4. the patient would never leave the Intensive Care Unit for the rest of his/her life;**

5. there is clear and convincing data to indicate the lack of a successful outcome (quantitative futility)—e.g., APACHE scores, multi-system (three or more) failure in elderly patient, CPR in patient with multi-system disease, etc.;**

6. treatment provides physiologic effect but no benefit; or

7. treatment offers no realistic, reasonable expectation that the physician's medical goals and the patient's personal goals and values can be realized (requires awareness of one another's goals and concurrence).**

* requires communication between physician and patient's surrogate.

** requires communication with, and concurrence of, patient or surrogate.

Guiding Principles

1. Under no circumstances will pain relief or such care as to maintain the patient's comfort and dignity be withheld or withdrawn.
2. Decisions about futility or the withholding or withdrawal of care should not be made by the attending physician alone, but should include the advice and consultation of the treating team staff, consulting physicians, and a formally constituted, multi-disciplinary committee where appropriate. Such decisions could also be made in accordance with an established policy in the local community.
3. A local multi-disciplinary committee should be used to consider and define instances of medical futility in order to provide a consensus that assists physicians and patients or surrogates in making futility decisions. Such a committee could function in a "dispute resolution" role where consensus cannot be achieved among members of the treating team and consultants or where the patient, family, or surrogate refuses to concur in the recommendation to withhold or withdraw treatment.
4. The Ethics Advisory Committee (EAC) or a subcommittee of the EAC could serve in the role of facilitating or arbitrating decisions concerning futility. To serve in this role the EAC should be expanded beyond its traditional membership to include expertise in outcome assessment or epidemiology where appropriate and available.
5. Without a mechanism for the development of consensus concerning medical futility, physicians could make ad hoc decisions that may be overly influenced by individual bias. Also, the application of an institutional consensus can protect the patient from burdensome measures.
6. Definition of care that will not be provided should include that which is outside the limits of professional standards, that which is negligent, and that which compromises the physician's integrity.
7. The approach to withholding and withdrawing treatment presented here is based on the understanding that resource

allocation and rationing issues ought to be separate health care issues—if cost is to be a factor in withholding or withdrawing care, it should be as the result of an established and explicit institutional or national policy and not determined on an ad hoc basis by a physician or health care administrator.

Future Directions

A. Immediate Goals and Continuing Emphasis

1. Increased emphasis on the VHA's Advance Directive and Durable Power of Attorney for Health Care.
2. Early and frequent communication between physician and patient or surrogate regarding diagnosis, treatment, prognosis, treatment goals, personal goals, and value system.
3. Increased use of "time-limited" trial to allow room for compromise, with frequent reevaluation of clinical state, time for the family to accept the prognosis, grieve, etc. This often serves to establish "futility" in the minds of all involved.
4. Use of ethics committees as sounding boards to mediate, offer support, guidance, etc.
5. Patient and professional education; patient empowerment.

B. Long Range Goals

1. More outcomes research to guide decisions in the future.
2. Development of treatment guidelines and policies based upon research and supported by professional consensus that the guidelines and policies should underwrite standard medical practices.
3. Awareness throughout the community of the concepts of limitations and fairness.
4. Evolution of societal consensus by the community as a whole about which treatments are not appropriate to offer or provide

under certain circumstances—the framework includes such elements as the value of life, the inevitability of death, professional responsibility, remorse, and social justice at a time when there are both increasing needs and demands as well as diminishing, limited, scarce resources.

5. Use of a facility multi-disciplinary committee to review generic cases and to develop policy defining treatments that are futile in particular clinical situations and advising that these treatments need not be instituted and may be withdrawn.

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2. Allocation of Expensive Medications

Ethical Principles for the Purchase and Use of Expensive Medications

- Veterans receiving care in the VA health care system should receive medically appropriate medications. In determining the appropriateness of a medication, cost is a factor.
- In those instances in which it is necessary, on the basis of either scarcity or cost, to restrict medications from patients who may derive some benefit, it is incumbent on the VA health care system to develop processes that ensure that the restriction will be fair and equitable.
- Therefore, strategies should be employed that ensure that veteran patients with comparable needs be treated equally. The goal of such strategies is to minimize discrepancies between various medical centers, while recognizing that discrepancies may continue to exist.
- Veterans at VA facilities that have unusual and above average needs for expensive medications should not be penalized because they compete against other veterans at that facility for resources. Mechanisms should be in place to respond to special burdens and permit equity in resource availability.
- The greatest flexibility should be exerted to find ways to minimize drug rationing. However, when limiting of beneficial medical treatments is required, decisions should be based on the overall needs of the entire veteran community.

Definitions

Expensive Medications

Defining "expensive medications" is difficult. A medication could be expensive because it is:

1. a single agent that costs a lot of money, e.g., $8,500 per year for one patient;
2. a less expensive agent provided to many patients; or
3. a medication with a low success rate.

Another relevant factor would be the impact of distribution of a medication on a particular medical center's budget. Additionally, although some drugs may appear to be more expensive, a pharmacoeconomic analysis that includes factors such as reduced hospitalization and clinic visits may indicate that these advantages would offset the net cost of the drug. As an example, in Fall 1994, the Headquarters Executive Committee on Therapeutic Agents considered a drug a "high expense agent" when it costs $8,500 per patient per year, based upon the appearance of numerous new medications costing this amount.

Methods of Economic Analysis

Cost-Minimization Analysis - CMA

The research methodology called Cost-Minimization Analysis (CMA) is the easiest to understand and is widely used. The essence of CMA is that it compares the cost difference between alternative therapies that are known or assumed to result in identical outcomes. CMA is analogous to the kind of decision-making process one uses while shopping. If you compare two items and ultimately conclude, based upon all available information, that the two items are identical, price would be the only factor differentiating the two. So, you would choose the least expensive.

Cost-Effectiveness Analysis - CEA

When equivalence of performance is questionable, Cost-Effectiveness Analysis (CEA) should be used. CEA quantifies differences in both costs and consequences and is appropriate when the

consequences of therapies are different. It measures both the incremental cost between alternative therapies and the differences in the health benefits each produces. CEAs are widely used because of their ability to directly compare different forms of therapy. In addition, stating inputs in monetary terms and outcomes in natural units makes their findings useful to both payers and providers.

Cost-Benefit Analysis - CBA

Cost-Benefit Analysis (CBA) also evaluates both cost and consequences. All outcomes are monetarized, making it possible to express the findings as an easily understood ratio of dollars gained in benefits to dollars spent in costs. The problem with this analysis in medicine is that all outcomes (human life, pain, suffering) must be monetarized. Some variables are very difficult to monetarize, e.g., benign allergic reactions. It is difficult for human beings to make decisions based purely upon economic value: e.g., what is the dollar value of increasing the survival of a terminally ill person by an additional year? CBA is very helpful at a public policy level, because when funds are limited, it is reasonable to ask which program will achieve the maximum net social benefit.

Cost-Utility Analysis - CUA

Cost-Utility Analysis (CUA) calculates the price of inputs and uses non-monetary measures of outcomes. Outcomes reflect patient preferences for health states. For instance, consider a medication that produces a side effect in the form of an annoying but benign skin rash approximately 25% of the time. In CUA, this would be expressed as the cost per rash avoided compared with an alternative medication. The consequence would be expressed as a patient's preference, usually described by what percent decrement from ideal health this adverse event represents.

Guidelines

Headquarters Executive Committee on Therapeutic Agents

Ethical Responsibilities

As stated in the March 6, 1992, VA Memorandum No. 10-92-004 on the Executive Committee on Therapeutic Agents, it is the Department of Veterans Affairs' responsibility to assure that every effort is made to treat all patients with safe, efficacious, and cost-effective therapeutic agents. This requires a continuing review of drug utilization and prescribing practices to be conducted by the VA Headquarters Executive Committee on Therapeutic Agents (ECTA) and by the Pharmacy and Therapeutic Agents Committees (P&T committees) at each VA facility. Generic drug procurement is required whenever feasible.

The Headquarters ECTA is also responsible for developing a mechanism to review and evaluate the use of expensive drugs in the VA health care system. This information should then be distributed throughout the system to inform VA facilities about practice patterns when using expensive medications. Local facility policies and procedures that have been developed for making these difficult allocation decisions should be collected and distributed. If national data suggest the possibility of inequitable or inappropriate use, ECTA should bring this to the attention of local facilities and their P&T committees.

Ethical Situations

a. Problem: Limited Supply

The goal of equal access to expensive medications is an important imperative in the VA health care system. When the problem in achieving full access is shortage of supply of the expensive medications, the most equitable mechanism for distribution is a centralized mechanism that considers together all veterans who satisfy the selection criteria for the drug.

A suggested method for making this form of distribution operational would be for the ECTA to direct the development of patient clinical eligibility criteria. Local VA facilities would then

identify specific patients who meet the criteria and submit those names to ECTA. ECTA would then select recipients of the medication using a lottery. This method is an arguably just approach. For patients not selected through the VA lottery, VA staff should assist those patients to obtain medications through other than VA mechanisms.

b. Problem: New Ethical Dilemmas

New ethical dilemmas will periodically arise for ECTA. The VHA Bioethics Committee will identify members with expertise who can assist ECTA to evaluate the dilemma and look for solutions that are based upon generally accepted ethical principles. ECTA would also benefit from utilizing the considerations recommended below for local P&T committees. Additionally, utilization of an ethical decision-making process would assist the discussion.

Local VAMC Pharmacy and Therapeutics Committees

Ethical Responsibilities

a. Treat all patients with safe, efficacious, and cost-effective therapeutic agents.

In accordance with VA Memorandum No. 10-92-004, local Pharmacy and Therapeutics (P&T) Committees must adhere to the following guidelines:

- Consideration must be given to fluctuating drug prices.
- Generic drug procurement is required when available.
- The purchase of high cost drugs cannot be justified when equally safe and effective but less expensive preparations are available, except under unusual circumstances.

Each VA facility is forced to make difficult decisions regarding the purchase and prescription of both “less expensive” and “expensive” medications. With both of these categories of medications, the P&T Committee will have to consider issues of cost and perform a cost evaluation. The Committee should therefore have expertise in the areas of pharmacoeconomic analysis and ethics.

b. Develop a representative committee.

Headquarters is committed to supporting the P&T committees at individual VA facilities. The long standing policy of not rigidly restricting professional practice by administrative direction from Headquarters continues. Local P&T committees should include a broad based group of professionals with appropriate expertise. Members should represent individual characteristics of medical center and clinic populations. Policies will be reflective of professional clinical judgments from individual centers.

c. Establish an ethical process to guide allocation of expensive medications.

To provide patients with medically appropriate, expensive medications, it is recommended that the P&T committee create a process for handling expensive medication allocation decisions. The process should be based on the ethical principles presented at the beginning of this report. Decisions by the P&T committee concerning expensive medications should be consistent with the mission of the facility.

A clinical, ethical, and economic analysis should include at least the following considerations:

- Practice guidelines:

  The P&T committee should develop practice guidelines for the usage of expensive drugs, e.g., indications for when and when not to use, which populations will be treated, efficacy, safety, whether only certain physicians can prescribe or approve the use of such drugs, etc.

- Comprehensive cost evaluation:

  This consideration requires factoring in subjective variables such as quality of life, positive outcomes of the drug usage, and fewer admissions, rather than just looking at the absolute cost of the drug.

- Community standards of practice:

VA patients should receive care at least equal to that practiced in the general medical community.

- Local institutional needs:

  If a P&T Committee determines that patients will suffer serious harm by being deprived of an expensive medication, and no reasonable alternative treatment is available, and the facility is unable to provide the necessary funding, the committee is responsible to carry out the following steps. Every effort must be made to divert funds for the medication from discretionary items. If this cannot be accomplished, the facility may propose that there be a redistribution of funds in the VA health care system. This would apply when it could be demonstrated that an individual facility had an unpredictable number of patients whose clinical circumstances warranted the use of the expensive medication, e.g., a station with a high prevalence of persons with AIDS.

- Every decision made should be accompanied by a cost statement.

d. Monitor and evaluate.

The local P&T committee should have a mechanism to monitor and evaluate the use of expensive drugs. Data should be gathered on patients treated, their clinical outcomes, and costs to the facility. The committee should also perform an annual review of both new and old “expensive” drugs to evaluate whether the drugs are meeting their original purpose and whether more appropriate or effective therapies have become available. The committee should develop a list of “triggers” that would initiate a review of the use of medications, e.g., an abrupt increase in spending relative to a single drug or a class of drugs; changes of pharmacy costs; or twenty drugs constituting 80% of the pharmacy budget.

The committee should also be alert for discrimination against any subset of patients. The committee should be willing to share its materials so that practice patterns can be shared broadly

throughout the VA system, enabling medical centers and outpatient clinics to learn from each other.

e. Create an appeals process.

An appeals process should be developed to consider requests for a second review.

f. Assure continuity of service.

When patients transfer between medical centers, every effort should be made to provide continuity of care, including the use of expensive medications when appropriate.

g. Provide for fee-basis physician orders.

If a fee-basis physician orders an expensive medication that is not on the hospital's formulary, there should be a process for evaluating the request, based upon the individual's specific need. The VA facility would need to be primarily responsible for the patient. The order could then be approved by the facility. Subsequent medication orders would be written by the authorized fee-basis physician in conformance with all VA clinical guidelines.

Case Study

VHA and the Use of Erythropoietin: An Example of an Expensive Drug Distributed with Local Discretion and Central Guidelines

Human erythropoietin (trade name Epogen) is a naturally occurring protein that stimulates the bone marrow to synthesize red blood cells. Its appearance created an important therapeutic opportunity (and challenge) to develop priorities for usage. Providers needed to maximize its effectiveness while avoiding expenditures that would impose inappropriate limitations on other medical spending.

The drug was approved in 1989 for the treatment of anemia seen in patients undergoing chronic hemodialysis. It was shown that the administration of erythropoietin was associated with other increased functional capabilities in these patients, and it was soon evident that erythropoietin was also of benefit to groups of patients with diseases in which anemia played an important part, e.g., patients with AIDS and

other malignant diseases receiving chemotherapy.

Since the drug costs $8,000 – $10,000/patient/year, treatment of every patient who might gain some benefit would constitute a very costly undertaking. Accordingly, each VA Medical Center developed policies for its use, through a process for dealing with expensive drugs that would take into account the need within that hospital for the drug, the local budgetary situation, and the impact that this expenditure would have on funding for other medical programs.

In addition to this local process, VA Headquarters played a role in guiding the utilization of this drug. Headquarters engaged the National Center for Cost Containment to analyze the use of erythropoietin by dialysis units throughout the system. The VHA Medical Service Ad Hoc Advisory Group on Renal Disease and Dialysis defined a group of guidelines for its use. On May 5, 1994, the Office of Clinical Programs distributed a Program Letter entitled "Guidelines for the Use of Recombinant Human Erythropoietin (r-HuEPO)," which dealt with the use of the drug both with dialysis patients and AIDS patients. This letter not only provided guidelines for its use but also provided information designed to maximize effectiveness and minimize cost in the patients designated to receive it.

In addition, in an effort to encourage an equitable distribution of the drug to veterans throughout the VA system, VA Headquarters distributed data indicating the use in each station. This permitted each VAMC to make a judgment about whether its usage and expenditure for the drug was in line with the general practice throughout the system.

The manner in which VHA dealt with this expensive drug illustrates several important ethical principles. The system found a reasonable middle ground between a tightly mandated, centralized policy for the distribution of the drug vs. policies dependent totally on local discretion that would make no attempt to provide equity across the system. In addition, local VAMCs were given the advantage of consultative expertise developed centrally, and the opportunity for reexamination of their own policies by comparison to the decisions made in other institutions throughout the system.

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3. Ethical Considerations in Equitable Allocation and Distribution of Limited Health Care Resources

Introduction

The purpose of this report is to identify relevant conceptual and pragmatic considerations for the development of strategies for the equitable allocation and distribution of resources. In the following discussion we make two presumptions regarding limited health care resources.

We *presume* that the current allocation of resources in the national economy is relatively fixed between competing major federal funding categories such as education, health care, defense, and social services. This presumption rejects the facile solution that rationing of scarce health resources may be avoided by simply moving funding from one major category to another to increase total funding for health care.

We *presume* that wasteful practices occur in the allocation and distribution of health care resources, which may limit some beneficial services. We reject the claim that if waste in health care delivery was eradicated, resources would no longer need to be limited. Reducing waste is an ethical imperative. While waste in health care is being reduced, covert and widely divergent rationing strategies will occur. Therefore, explicit practices that fairly allocate and distribute health care resources are necessary, as well as practice guidelines and other means to control inefficient or wasteful practices.

Informed discussion of equitable allocation and prudent distribution of limited health care resources needs to acknowledge the contemporary societal factors that are promoting the larger discussion of health care reform within both VA and the private sector. Health care reform and the related issues of allocation and rationing have recently been given a higher societal priority for a number of reasons. These include, but are not limited to: limited access to care by millions of Americans; increasing health care expenditures; wide variation in utilization of health care services without appreciable differences in outcomes; use of expensive technologies and treatments with marginal benefits; fear of catastrophic personal consequences associated with treatment for illness; a culture that embraces seeking treatment for every ill; loss of insurance due to change of employment; loss of coverage due to heavy usage; inability to obtain coverage because of pre-existing illness; and limited insurance coverage for home, outpatient, psychiatric, and long-term care. These societal concerns may or may not always overlap with issues of equity or fairness. The determination of fairness in allocation and distribution requires critical analysis. Simple cost containment measures may not provide equitable solutions. Even if some consensus is achieved regarding what constitutes equitable or fair procedures, some individuals will continue to view the procedures as unfair because they still have health care needs that are unmet while other individuals are receiving health care resources for their needs.

Definitions

To facilitate our discussion of equitable allocation and distribution of limited health care resources, we offer definitions or clarifications of the following terms and concepts.

Equity

The principle underlying equity is impartiality or fairness. However, fairness may be interpreted in many ways depending on one's political and philosophical perspective. From a libertarian perspective, fairness would allow any individual who developed capital

worth through legitimate means to purchase whatever health care services he/she desired. An egalitarian would believe equal access to health care for those with equal needs to be a requirement of fairness. In our discussion, we assume more of a contractarian position in which equity would imply provision of whatever resources any rational person would desire if they were ignorant of their personal attributes and status in society. This form of distributive justice has been described by Rawls and is often demonstrated by developing rules behind "a veil of ignorance."

Allocation

Allocation occurs when monies or resources are distributed across competing venues. Health care represents one venue. Defense and education, for example, are two other venues with which health care competes.

Rationing

Rationing is a system of rules for limiting beneficial and scarce resources among those individuals who have a claim on those resources by limiting availability and/or utilization. Patient-centered rationing limits particular individuals or groups from access to selected treatments, e.g., elderly people from dialysis, terminally ill people from intensive care units, people with a history of alcohol abuse from liver transplantation. Resource-centered rationing limits access to certain resources, e.g., regionalization of MRI scanners to which individual medical centers may have shared or limited access.

Cost Containment

Cost containment is the limitation of health care spending, achieved through strategies to control the increasing share of health care expenditures in relation to the GNP or other sectors of the national economy.

Scarcity

Scarcity is the shortage of a good for which there is a dire need. Resources may be finite, but not scarce. Scarcity implies greater

demand than availability, while finitude refers only to the resources' availability and does not take into account the demand.

Basic vs. Non-basic Care

The definitions here may differ significantly from what is included in certain basic benefit plans. Also, comparisons of basic and non-basic care often presuppose theoretical and value-laden distinctions between levels of treatment that have not been stated and often lack community consensus. These reservations stated, we present basic care as preventive, curative, and rehabilitative treatment that has proven efficacy and compensates for deficiencies in the range of normal biological and social opportunities persons enjoy at each stage of life. In contrast, non-basic care either aims to improve conditions unrelated to normal opportunities, or it aims to correct or compensate for deficiencies in normal opportunities, but it is marginally effective or ineffective in doing so. Therefore, non-basic care is discretionary, often with questionable benefit, and is supererogatory. For example, a diagnostic test that does not change therapy, a life-sustaining treatment which merely prolongs the dying process, and some cosmetic surgery all qualify as non-basic care. By limiting the distribution of non-basic health care, resources may be conserved and may help to ensure access to at least a minimum level of basic health care for all veterans. The distinction is emphasized to prevent artificial inflation of the costs of basic care by including under this category care that would more appropriately be labeled non-basic.

Education for the Health Care Consumer about Limitations

The financing and structure of health care delivery strongly affects the process of care. Autonomy has been valued highly in our health care system, as have the physician-patient relationship and the role of the physician as the patient's advocate. But with increasing emphasis on cost containment and expanding access and availability of care to all, and the recognition that resources are limited, constraints may need to be placed on the patients' choices. The public must be educated about the need and justifications for limitations. Society will more likely

approve of limits when everyone is contributing equitably. Our society must be asked to re-evaluate its unrealistic emphasis on health services as the principal source of happiness or good health. Of particular concern are the misperceptions that veterans may have about the extent of health care benefits to which they are entitled. Consensus must be encouraged about care that is of such marginal utility that society can and must refuse to support it economically and morally. Medical care that merely prolongs the dying process should be discouraged for all age groups. The most desirable health care policy is one that mandates comprehensive benefits, meets the basic needs of most individuals, and is cost-effective.

Ethical Considerations in Allocation and Distribution

1. Limiting access to beneficial health care services should occur only when there are inadequate resources to meet the need. Resources include treatments, diagnostic tests, space capabilities, personnel, and finances.
2. If resources are saved as a result of rationing, the savings should serve to provide greater health care benefits to others.
3. Individuals with equal needs should have equal access to health care resources, and disparities in access due merely to geographic location should be minimized.
4. Patients' absolute power to dictate or demand a specific treatment must be tempered in the formulation of strategies for equitable allocation and distribution of health care resources. Respect for autonomy is exercised in the context of offering reasonable medical treatment.
5. The definitions and determinations of the following principal considerations should be developed, with representation from all interested and affected parties:
    - basic vs. non-basic health care,
    - medical benefits/burdens,
    - patient responsibilities, and
    - medical futility.

6. In reaching an allocation or distribution decision, management should actively consider other equally deserving and meritorious needs, including those not being forcefully advocated.
7. New and technologically innovative treatments are attractive to providers and consumers alike. These are often costly and have the potential to add significantly to health care expenditures without necessarily having greater effectiveness than treatment already available. Therefore, new technologies should be included in VHA's armamentarium only after they are shown to be more effective or more cost-beneficial than current therapies.
8. By the same token, currently used diagnostics or therapeutics shown by outcome studies not to be effective should be eliminated.
9. A clear and honest determination and reorganization of the several missions within each Veterans Integrated Service Network (VISN) is required.
10. Non-clinical criteria for patient care eligibility create ethical dilemmas that require thoughtful consideration.

Procedural Considerations in Allocation and Distribution

1. Equitable strategies for allocation and distribution of health care resources should be explicit, public, and accessible.
2. These strategies should be developed with representation from all interested and affected groups. This assures that assessments of benefits and costs are not limited to the views of a single group and a single time frame.
3. Strategies for rationing care that focus on patients' characteristics (patient-centered rationing) should be used only when resource-centered rationing strategies prove to be inadequate. Patient-centered rationing strategies should focus on the magnitude of patient-centered medical benefit and avoid social worth criteria (age, sex, race, education, social class, productivity). Queuing on the basis of relative medical benefit to an individual as a means of rationing health care is a morally justifiable and acceptable policy.

A queuing strategy for allocation should take into consideration possible inequities that will arise due to unfair (dis)advantages associated with physical or mental disability, education level, access to information about available treatments, sophistication in obtaining treatment, financial status, etc.

4. If all other criteria are equal, those individuals with equal need and anticipated benefit may be selected for treatment by use of a lottery.

5. Quality assurance mechanisms need to be developed to evaluate and monitor allocation and distribution strategies to ensure that the fiduciary relationship between physicians and patients is not compromised by changing financial and delivery structures in the competitive health care marketplace.

6. Policies and strategies need to be revised frequently because new technologies and changes in availability may modify the current conditions.

Case Examples

These case examples were derived from stories from the field related by subcommittee members. They have been selected because they illustrate important ethical concerns. The committee is aware that in modifying them for presentation we have oversimplified some VA or DoD procedures.

Case 1

The director of the medical center must make a choice between the following two requests.

First Request

The chief of ophthalmology requests purchase of a binocular multiheaded operating microscope to teach and supervise residents in performing lens implants. With the binocular scope, the surgery could be performed more quickly and efficiently. Currently, the eyesight salvage on cataract patients is at least 400 to 500 patients per year. The cost of the microscope alone is $145,000.

Second Request

A VA patient who has had a heart transplant at a distant VAMC moves into this area to be near his parents and requests treatment at the local VAMC. His father is a Regional Office Director for the Congressional Representative. The patient is a Gulf War veteran who contracted viral myocarditis with rapid deterioration during the war. The VA medical center near his parents has not budgeted for the cyclosporine therapy and other anticipated or potential medical/surgical treatments required to maintain his transplant at a cost of $148,000 per year.

Ethical Considerations

The medical center director must make a choice because he has exhausted his designated equipment budget and must reallocate resources from another fixed budget source. The total amount of resources is finite. The binocular microscope will make it possible to treat 20-25% more patients (100 individuals) than are currently treated. In addition, the entire group of cataract patients will receive greater medical benefit because there will be overall fewer surgical complications, although the degree of this benefit is uncertain. The community will also benefit because these elderly patients will have substantially improved vision. They will be able to care for themselves more completely and require less assistance for their day-to-day needs. The treatment is considered "basic care" that has proven efficacy and allows the patients to enjoy the normal opportunities at their stage in life. Although the microscope is a one-time expenditure, the costs of surgery for the additional patients in each year will need to be considered and represents a commitment to future expenditures. The mission of this local VAMC includes education of surgical residents, and it is expected that some expenses will be incurred to provide a better learning environment.

In the second situation, a single identified individual has already been provided with sophisticated surgical care and VHA has an obligation to provide follow-up treatment. It is not clear that VHA should be obligated to minimize disparities in access due to geographic

location by providing his treatment locally, no matter where the patient chooses to live. The patient's right to self-determination and his choice to move nearer to his parents for his own convenience may need to be subjugated to the overall health care mission of the local VA hospital where he is now seeking care. This patient has a service-connected illness which was not directly caused by the performance of military duties. It was anticipated that his transplant and good follow-up care would provide significant (life-saving) benefit to the patient. He is relatively young and has a moderate chance of returning to full-time employment, and that prospect may be seen as a benefit to his family and the community. The requested expenditure is not a one-time allocation, but a recurring annual expense. The VAMC near his parents does not have as part of its local mission the provision of acute or long-term care for patients requiring organ transplants. The director expects that the patient's father may attempt to exert some influence through his political connections to get care for his son.

Procedural Considerations and the Director's Decision

After open discussion with the chiefs of ophthalmology, cardiology, rehabilitative medicine, pharmacy, and subspecialists at the tertiary care VA, the director decides to purchase the microscope. Although the transplant patient is an "identified" patient, the cataract patients are not a nameless group, but are currently being seen in clinic and can also be "identified" individually as needing surgery. Furthermore, future cataract patient load can be reliably predicted based on data from the past several years. The financial outlay of the two requests will be relatively equal each year. The additional costs related to surgery for the cataract patients will roughly equal the yearly cost of cyclosporin. However, rehabilitation costs for "blind training" for cataract patients that will not be required if they have surgery represent a potential cost savings for a different service.

A large group of patients will have significant medical benefit from the cataract surgery who would otherwise have had to wait a lengthy period prior to operation. Their overall outcome can be relatively accurately predicted. They are for the most part elderly and the length

of benefit for each patient may be only 5 to 10 years. The transplant patient has had life-saving benefit from his transplant and may attain near normal life function. However, his medical outcome is less certain and his ultimate life span may be no longer than that of the cataract patients.

The director believes strongly that VA has a special obligation to veterans with service-connected disabilities and that they should receive some priority in access to health care within VHA. He also understands that it is not within the scope of his VAMC's mission to provide follow-up care for transplant patients, and to do so would require him to limit care to some other group of patients in his medical center to whom he has already made a commitment. After discussion with the transplant patient, he agrees to provide travel funds for two visits per year to the tertiary-care VAMC, where the patient will obtain a six-month supply of cyclosporin and other medications and see the appropriate subspecialists for follow-up. The local VAMC cardiology service will see the patient regularly in clinic and monitor his progress. If he requires hospitalization related to his transplant, he will be sent to the tertiary-care VAMC. Funds will not be provided to his family for travel to accompany him. Although the director expects to hear from the member of congress, he believes his decision can be ethically defended and feels a responsibility to those patients already in the care of his VAMC who may not have powerful advocates.

The cataract patients will be queued for surgery. Priority will be given based on the magnitude of patient-centered medical benefit. This plan will take into consideration their other diagnoses, overall prognosis, prognosis for vision restoration with surgery, and other treatment options. For example, patients with diabetes who may have visual loss related to their disease will not be offered surgery or will be placed at the end of the line. This method of prioritization will be explained to each patient presenting with cataracts who may need surgery.

Case 2

Hospital budgets in Region X are severely reduced. Personnel chiefs

working with medical center directors cut occupational and physical therapist staffs by 50%. In response to the reduction in staffing, the chiefs of rehabilitative medicine service (RMS) in Region X met to assign priorities to the types of patients for whom their services would continue to provide care.

The chiefs agreed that they would no longer accept transfers from a military hospital of personnel with acute closed-head injuries who are on active military duty. (For the purposes of this case, we will assume that these patients are not immediately discharged from the military.) These patients normally require three months of acute rehabilitation at approximately $400 per day and an additional two months stay in a specially-staffed nursing home at $110 per day (a total of $42,600 per case). VHA has allocated only $9,000 per case to treat such patients and will not increase funds provided to the local VA medical center if costs exceed this limit. The unreimbursed expense to the individual VA medical center for each of these patients would be $33,600.

The average number of such patients (almost all under forty years of age) in Region X is 20 per year, resulting in an average expenditure per year of $672,000.

The chiefs of RMS preferred to apply these funds to rehabilitation of stroke patients who had potential for partial return of function and discharge to their homes. The average number of patients in this group is 500 per year and all are 60 years of age or older.

Ethical Considerations

Since their resources are finite, the chiefs of RMS in Region X must reduce their case load to accommodate the decrease in staffing. To accomplish this, they must limit access to beneficial health services for some group of patients. To justify rationing care, they must show that the savings will provide greater benefits to others, in this case the stroke patients.

Clearly the group of patients with head injuries will benefit from the treatment, which would be considered basic care. Most of them

will have full return to function and, since they are relatively young, they may have a number of productive years ahead of them. No one would suggest that they be denied care for their head injuries, but it is not at all clear that VA has as part of its mission the provision and financial underwriting of care for individuals on active military duty. It seems even less likely that individual VA medical centers would consider this part of their local mission and would be willing to divert funds from veterans in their care to support care of active duty military patients in peacetime. The head-injured patients have a powerful advocate in the Department of Defense, and the VHA personnel involved in this allocation decision need to actively consider the equally meritorious needs of other patients to whom they already have an obligation and who may not have forceful advocates.

The stroke patients also will benefit from the rehabilitative care, which would be considered basic care. Their medical outcome will be only a partial return to function, but it may enable them to resume personal care for themselves and make them less reliant on family and community resources in the long term. Their advanced age and partial return to function means that it is unlikely that any of them will return to the workforce, but they will be able to enjoy many of the normal opportunities at their stage of life. The large number of patients who would benefit from this rehabilitation will be reflected in significant cost savings for future VA and community resources.

Procedural Considerations

The decision-making process followed by the directors and personnel chiefs in making budget cuts seems to be ad hoc rather than based on a carefully thought out health care plan. As the case was described, they did not consult with either the chiefs of RMS or the occupational or physical therapy health care staff regarding their decision and its impact on patient care. The RMS chiefs continued this pattern by not consulting with their staffs or including military personnel in their decision-making process. Neither allocation/rationing decision was made in an explicit, public, and accessible manner, nor were representatives from all affected groups included in the process. Assessment of benefits and costs was limited to a small circle of individuals.

The rationing strategy used by the RMS chiefs could best be described as patient-centered, since they chose to ration (deny) care to a group of patients based on their clinical characteristics. To use this rationing strategy, one should focus on the medical benefit to each individual patient. In fact, if one compares the two groups under discussion, head-injured versus stroke patients, the head-injured patients would be most likely to have the greatest individual medical benefit from treatment. The social worth issues of younger age and higher productivity should not be used to justify choosing this group for treatment, nor should they be used to discriminate against the older less productive stroke patients.

The RMS chiefs cannot ethically justify their selection of the stroke patients over the head-injured patients based on individual medical benefit. The only defensible ethical basis for their decision must arise from their duty to give veteran patients priority for health care as part of the mission of VA and the local VA medical center. However, unilaterally refusing to provide care to the head-injured active military patients without assisting in developing a plan for care for future patients of this group would be abandoning patients for whom VHA, at some administrative level, has agreed to provide care. If budgetary constraints prevent a VA hospital from continuing to provide this care, then the system needs to search for other creative solutions that would enable the hospital to transfer care of these patients. These solutions could be sought internally within VHA or externally through a sharing agreement with the Department of Defense. In conclusion, although the decision that some rationing of care may be necessary and can be ethically defended, the procedures used for making rationing decisions in this case do not stand up to ethical scrutiny.

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4. Guidelines for the Allocation of Unproved Treatments

Background

All systems of health care have finite resources. No health care system can provide every item or service that might be desired by its patients or practitioners. Therefore, allocation decisions concerning how and where to spend the finite resources are inevitable in every health care system. Opportunity costs are incurred whenever allocation decisions are made. Opportunity costs refer to the fact that a decision to expend health care resources on one particular meritorious item or service implies the inability to expend those same health care resources on other competing potentially meritorious items or services.

Because of these opportunity costs, allocation decisions have ethical dimensions. The positive and negative impacts on patient health care resulting from expenditures on competing goods and services must be analyzed. Allocation decisions involving a choice between competing meritorious health care expenditures should include a utilitarian assessment of the resulting relative benefits and burdens to patients within the system.[1] Unproved treatments remain a controversial category of health care expenditures that incur opportunity costs. Experimental pharmaceuticals or other unproved therapies of alleged efficacy may be requested by patients or physicians outside of approved clinical-scientific trials. These unproved therapies often are expensive, scarce, potentially harmful, and of uncertain benefit. Indeed, because the outcomes of their use are unknown, ultimately they may cause

harm rather than benefit to the patient. Given their direct costs and opportunity costs, uncertain benefits, and potential for harm, what is the ethical duty of a health care system to provide unproven treatments?

Charge

The Subcommittee on Allocation of Unproved Treatments was charged by the VHA Bioethics Committee to study the ethical duty of VHA to provide unproved treatments to its patients and to formulate the principles governing the provision of unproved treatments.

Scope

This report concerns unproved therapies that may be requested by patients or their families, and occasionally may be requested by physicians, but for which no current mechanism exists for their provision. The class of unproved therapies forms a broad continuum of different treatments, all of which share the characteristic that their efficacy and safety have not been proved scientifically. On one end of the continuum stand those therapies anecdotally alleged to be beneficial, but for which no scientific evidence whatsoever exists for their efficacy or safety. On the other end of the continuum stand those therapies for which preliminary scientific evidence exists for efficacy and safety, but which have not been validated fully and therefore cannot yet be considered accepted medical therapies.

Many therapies on the anecdotal pole of the continuum have been labeled “alternative” or “folk” therapies because usually they arise from cultural or other popular, nonscientific sources. These alternative therapies may be requested by patients or their families as a consequence of their belief and hope that these therapies can be effective and safe when scientific therapies have failed, when scientific therapies are unavailable, or when scientific therapies are likely to produce undesirable side effects. Within some cultures, particular alternative therapies may have achieved an anecdotal popularity and desirability that is grossly disproportionate to the valid evidence of their safety or efficacy. A physician’s decision to consider providing

such alternative therapies requires a careful consideration of the relevant principles of clinical therapeutics as well as an understanding of the principles of justice.

Some therapies on the opposite pole of the spectrum have been called "emerging scientific" therapies. There is a continuum between emerging scientific therapies and accepted medical practices. Emerging scientific therapies gradually evolve from the laboratory to the clinic as evidence accumulates for their efficacy and safety. It is not intuitively obvious at which point along that continuum to draw the line separating an unproved emerging treatment from an accepted medical practice.[2] Therefore, adequate guidelines should acknowledge the reality of this continuum, apply equally well to multiple points along it, and not attempt to stipulate the point at which an unproved emerging scientific therapy becomes an accepted practice.

By intent, this report will not focus on therapies currently under active scientific investigation because existing programs and policies already provide guidance and mechanisms for the provision of such agents. For example, patients requesting this class of agents can be enrolled in approved clinical trials of the agent, can receive the agent through a "parallel track" mechanism if they cannot or choose not to participate in clinical trials, or can receive the agent from the manufacturer through a program of "compassionate use" outside of approved experimental protocols. When possible, patients requesting unproved therapies should be encouraged to enter clinical trials.

Standards

There are four fundamental principles or standards that form the backbone of the analysis of VHA's ethical duty to provide patients with unproved treatments. These standards are complementary. Each should be taken into consideration in a decision whether to provide unproved treatments. There is a hierarchy of importance of the standards. In descending order of their usual importance:

1. **The Standard of Efficacy**

   VHA's ethical duty to provide its patients with a particular unproved therapy for a particular disease increases as the evidence for efficacy of that therapy increases for the treatment of that disease.

2. **The Standard of Unreasonable Burden**

   VHA's ethical duty to provide its patients with a particular unproved therapy for a particular disease decreases as the burdens of that therapy increase for the treatment of that disease.

3. **The Standard of National Practice**

   VHA's ethical duty to provide patients with a particular unproved therapy increases as the evidence increases for its recommended use in accepted clinical practice guidelines drafted by expert panels.

4. **The Standard of Community Practice**

   VHA's ethical duty to provide its patients with a particular unproved therapy for a particular disease increases as that therapy becomes a community standard of practice for the treatment of that disease.

The Standard of Efficacy

There is a direct relationship between the evidence that an unproved therapy is effective and the ethical duty of VHA to provide it. With no evidence of efficacy, there is no ethical duty to provide it. With only preliminary, unconfirmed efficacy data, there is only a small duty to provide it. As more valid data are accumulated, the duty to provide it grows proportionately. Once there are adequate data to permit routine use of the therapy, the ethical duty to provide it becomes very great.

Efficacy outcomes for disease treatment can be measured either by the prolongation of life or by improvements in the quality of life. The efficacy standard can be applied accurately only when professionals with the clinical competency to properly provide the therapy are available.

The standard of efficacy should take into account the relative efficacies of alternative therapies available for the condition in question.

The Standard of Unreasonable Burden

There is an inverse relationship between the evidence that an unproved therapy is burdensome and the ethical duty of VHA to provide it.

Relevant burdens in this regard include the risks to the patient posed by the therapy and the direct and indirect costs of the therapy to VHA. The reasonableness of bearing the burdens will vary depending upon the severity of the illness in question.

As is true in all therapeutic decisions, the foreseeable risks of the unproved therapy must be balanced against its potential benefits in a utilitarian analysis. Only if the anticipated risks are justified by the expected benefits should the therapy be employed. Risks include all the expected or potential untoward consequences of the therapy, both physical and psychological. Risks also include the loss of benefits that may have resulted from the use of accepted and potentially effective therapies that were abandoned in favor of the unproved therapy. Additional risks to the patient may be produced if health care professionals lack the requisite clinical competence to correctly administer the proposed therapy.

The costs incurred by VHA include direct expenses, indirect expenses, and opportunity costs. The direct expenses refer to the monetary costs of providing the therapy. Indirect expenses include at least the costs of providing protection for legal liability for complications of the unproved therapy, and the costs of treating complications of the unproved therapy. Opportunity costs refer to the inability of VHA to use the money spent on unproved therapies for other meritorious goals.

The Standard of National Practice

As scientific therapies evolve in the transition from investigational to accepted practice, expert panels often publish clinical practice guidelines for their optimal utilization, based on the available scientific evidence for their efficacy and safety. The existence of relevant expert panel guidelines should be sought, and those guidelines that are available should be studied, because they provide evidence of nationally accepted standards of medical practice.

The duty of VHA to provide these transitional therapies increases in direct relation to the force of accepted clinical practice guidelines recommending their use. Headquarters can assist local VHA facilities in the identification of accepted clinical practice guidelines and also by providing a means for tracking the expenses and outcomes of these treatments.

The Standard of Community Practice

VHA has an ethical duty to provide its patients care, or access to care, the quality and comprehensiveness of which parallels that available elsewhere in the community. This duty increases in direct proportion to the extent that a particular unproved therapy becomes a community standard of care.

There are certain conditions for which a community standard does not exist because of the uniqueness of the condition in veterans or because of its general rarity. For example, the medical complaints of Gulf War veterans and those of Vietnam veterans exposed to Agent Orange probably cannot have a community parallel. In these instances, the community standard should be omitted and the remaining standards employed in the analysis.

Issues of Community Risk

There is a direct relationship between the risk to other unaffected patients in the community posed by a patient with a particular serious disease and the ethical duty of VHA to provide unproved therapies for

that disease, which would diminish that risk. Serious diseases that are contagious produce harms to other patients that may be diminished by reducing the disease spread and prevalence. The dimension of community risk implies a special duty to try to develop treatments for these diseases that reduce their prevalence and thereby decrease their spread to unaffected individuals.

Decision-making for VHA Facilities

Each VHA facility should be given the authority to decide locally whether to fund a given unproved therapy. This decision should be based on the benefits and burdens of the proposed therapy, and on the four standards for decision-making enumerated above. Any proposed unproved therapy should be subjected to rigorous scrutiny on these points and standards.

Each VHA facility should be permitted to choose who within the institution will be authorized to render such judgments. In many facilities, the Pharmacy and Therapeutics (P&T) Committee, or a subcommittee of the P&T Committee, will be best poised to make the decision. Not all unapproved therapies employ pharmaceuticals. The processes for analyzing the standards of efficacy, burden, national practice and community practice are similar for pharmaceutical and other therapies. The P&T Committee, or its subcommittee, in most cases has the greatest experience in conducting this method of analysis.

An appropriate method should be established within eachVHA facility to review and resolve disagreements between those who request unproved therapies and the decision-making body.

Social and Political Influences on Decision-making

Social and political factors may be raised by patients or families that may influence the decision to provide unproved therapies. For example, the dramatic changes in FDA regulations concerning the development and clinical use of new therapeutic agents for HIV/AIDS have been well documented.[3] In VHA, these factors may influence decisions to offer specific unproved treatments for various disorders,

e.g., HIV/AIDS, Gulf War illnesses, PTSD, or other conditions with political and social dimensions. However, these factors are not as relevant as the four standards and thus should not be given priority over them.

Recommendations

1. Each VHA facility should establish a mechanism for deciding whether and how to offer a requested unproved treatment. In many VHA facilities, the P&T Committee or one of its subcommittees will most efficiently fulfill this charge.
2. The agents responsible for rendering such a decision should carefully investigate the likely benefits and the burdens of the proposed therapy to the patient, the institution, and the system.
3. In rendering a decision, the agents should perform a utilitarian analysis employing the following standards, in order of their usual descending importance: the standard of efficacy, the standard of unreasonable burden, the standard of national practice, and the standard of community practice.

Notes

[1] These propositions are defended in Eddy DM. "Principles for Making Difficult Decisions in Difficult Times." *JAMA* 1994;271:1792-1798.

[2] An attempt has been made to provide criteria to separate standard and experimental therapies. See Reiser SJ. "Criteria for Standard versus Experimental Therapy." *Health Affairs* 1994;13(3):127-136.

[3] Freedman B. "Nonvalidated Therapies and HIV Disease." *Hast Cent Rep* 1989;19(3):14-20.

Appendix: Examples Employing the Guidelines

1. Hyperbaric Oxygen Treatment of Multiple Sclerosis

   A. Background

   Hyperbaric oxygen treatment using a therapeutic environment of O_2 gas at greater than atmospheric pressure has been used successfully to treat gangrene produced by anaerobic bacteria and decompression illnesses resulting from N_2 diffusion in deep sea divers. To provide hyperbaric oxygen treatment, a suitably equipped steel compression-decompression chamber and several skilled personnel are necessary. Currently, there are only about 15 such facilities in the United States.

   The idea that hyperbaric oxygen treatment might be beneficial for multiple sclerosis (MS) was based upon a theory of the pathogenesis of MS. As had been true in many other novel therapies alleged to be beneficial in MS, no controlled study of its alleged benefit was carried out when the anecdotal preliminary reports of its efficacy were published.[1] Nevertheless, following the publication of these preliminary reports, largely because this therapy sounded effective and safe and because there was no alternative offering better results, MS patients and their families began to contact physicians to request hyperbaric oxygen therapy. How should VHA respond to an MS patient or family member's request for this therapy?

   B. Analysis

      1. *The Standard of Efficacy*

      There are only uncontrolled reports alleging efficacy of hyperbaric oxygen in MS. Controlled studies are necessary to determine efficacy, particularly in a disorder such as MS with spontaneous remissions. In the subsequent controlled studies, no evidence of efficacy was found.[2] Therefore, VHA has no duty to provide this therapy on the basis of efficacy.

2. *The Standard of Unreasonable Burden*

   Hyperbaric oxygen treatment requires the availability of a hyperbaric oxygen chamber and a staff to run it. The chamber itself costs in excess of $2 million and annual staff costs probably add another $1 million. The treatment entails some risk of neurological dysfunction resulting from overexposure to oxygen at high pressures. The direct costs alone likely represent an unreasonable burden to VHA, in the absence of any strong evidence of efficacy. There are good data that other therapies, such as glucocorticoid therapy, interferon-beta-1b, and other immunosuppressive therapies offer a greater benefit. Therefore hyperbaric oxygen treatment fails this test.

3. *The Standard of National Practice*

   The data supporting the use of hyperbaric oxygen treatment for MS were reviewed by the International Federation of Multiple Sclerosis Societies Therapeutic Claims Committee. They found no convincing evidence of efficacy and therefore recommended against any MS patient undergoing this therapy.[3] Therefore the treatment fails this test.

4. *The Standard of Community Practice*

   Hyperbaric oxygen treatment for MS is not a standard treatment in any community. Indeed, it is not available in the overwhelming majority of American communities for the treatment of any disease. Therefore it fails this test.

C. Conclusion

VHA should not provide hyperbaric oxygen therapy for multiple sclerosis, even when requested by MS patients or their families, because of the lack of its efficacy, its unreasonable burden on the patient and the system, the recommendations of an expert international panel, and the availability of other, more effective therapies.

2. Use of Oral Interferon-alpha in the Treatment of AIDS

A. Background

Kemron, also known as the African AIDS drug, is a natural leukocyte-derived interferon-alpha (IFNα) substance. Interferons generally are not believed to be orally bioavailable. They are rapidly denatured (broken down) upon contact with gastric secretions. For clinical use, IFNα is formulated with powdered maltose into powder or tablet.[4] Patients are instructed to retain the compound in their mouths, sublingually, for up to five minutes to allow absorption by the oral mucosa prior to swallowing.

The initial study of low-dose oral interferon-alpha (IFNα), or Kemron, for the treatment of HIV infection was conducted by Koech and colleagues of the Kenyan Medical Research Institute. According to the study published in the Journal of Molecular Biotherapy in 1990, 8 of 40 (20%) HIV-infected patients treated for six weeks with low-dose oral IFNα showed a loss of seropositivity on ELISA and Western blot tests.[5] In addition to the sero-deconversion (or sero-reversion), the authors reported that patients showed a substantial rise in the CD4+ lymphocyte counts and improvement in clinical symptoms. Similar results were reported by Koech and colleagues in two subsequent reports. The studies were criticized for the lack of scientific rigor and lack of quality control for the CD4+ measurements.

The results reported by Koech and his colleagues led to the use of Kemron in some HIV-infected communities, particularly African American communities, and prompted further clinical research. In response to the widespread use of Kemron and other forms of low-dose oral IFNα by many HIV-infected patients and the controversy surrounding their use, the AIDS Research Advisory Committee (ARAC) of the National Institutes of Health requested that all information available on

this form of therapy be reviewed and a report be prepared for the committee by staff of the National Institute of Allergy and Infectious Diseases (NIAID).

In March, 1992, the ARAC examined the NIAID report containing summaries of 13 well-designed studies of low-dose oral IFNα. The beneficial results initially reported by Koech and colleagues were not reproduced by other researchers. Specifically, these studies were unable to duplicate the increases in CD4+ cells and conversion from HIV seropositivity to HIV seronegativity as initially reported by Koech and his colleagues. Based on this review, the ARAC recommended against the use of low-dose oral IFNα in AIDS patients.[6] Patients and their physicians were encouraged to carefully review the value of Kemron and other oral IFNs and to seek treatment with therapies whose efficacies had been established in well-designed, controlled clinical trials.

Despite the controversy and the scientific community's stance against Kemron and other oral IFNs, HIV-infected patients continue the use of these compounds. As a result, another large oral interferon-alpha trial was planned.[7] Dr. Lawrence Deyton, then Director of the Community Programs for Clinical Research on AIDS (CPCRA), had taken the lead in planning and funding this trial.[8] According to a commentary in *Treatment Issues*, because the issue of the efficacy of oral IFNα has been settled scientifically, this trial represented a waste of precious dollars and goodwill.[7]

B. Analysis

1. *The Standard of Efficacy*

Only one clinical study, that of the Kenyan Medical Research Institute, reported encouraging results from the use of Kemron. That study has been criticized on scientific grounds since it was uncontrolled and open-ended. There is no scientific evidence of the efficacy of Kemron.

2. *The Standard of Unreasonable Burden*

   The effects of Kemron are unclear. There was no indication of side-effects or physiological harm to patients. However, the cost of a drug that is not efficacious must be considered. Further, the psychological "cost" of a drug which patients incorrectly perceive as beneficial is not readily calculable.

3. *The Standard of National Practice*

   The ARAC reviewed data from a number of clinical trials and did not support the use of Kemron. Rather, the ARAC recommended that Kemron not be used in the treatment of HIV infection.

4. *The Standard of Community Practice*

   The use of Kemron is not a clinically accepted standard of community practice. However, some HIV communities, particularly African Americans, use and advocate for treatment with Kemron.

C. Conclusion

VHA should not provide Kemron for patients requesting the drug because it fails to meet the above standards. Other clinically effective therapies for HIV/AIDS should be provided for treatment.

Appendix Notes

[1] Neubauer RA. "Treatment of Multiple Sclerosis with Monoplace Hyperbaric Oxygenation." *J Fla Med Assoc* 1978;65:101; Neubauer RA. "Exposure of Multiple Sclerosis Patients to Hyperbaric Oxygen at 1.5 - 2 ATA: A Preliminary Report." *J Fla Med Assoc* 1978;67:498-504; Baixe JH. "Bilan de Onze Annees d'Activitie en Medicine Hyperbare." *Med Aer Spatiale Med Subaquatique Hyperbare* 1978;17:90-92.

[2] Sibley WA, ed. *Therapeutic Claims in Multiple Sclerosis*, 2nd ed. New York: Demos Publications, 1988:159-160.

[3] Fischer BH, Marks M, Reich T. "Hyperbaric Oxygen Treatment of Multiple Sclerosis: A Randomized, Placebo-Controlled, Double-Blind Study." *N Engl J Med* 1983;308:181-186; Bames MP, Bates D, Cartlidge NEF, et al. "Hyperbaric Oxygen and Multiple Sclerosis: Results of a Placebo-Controlled, Double-Blind Trial." *Lancet* 1987;1:297-300; Harpur GD, Suke R, Bass BH, et al. "Hyperbaric Oxygen Therapy in Chronic Stable Multiple Sclerosis: Double-Blind Study." *Neurology* 1986;36:988-991; Bames MP, Bates D, Cartlidge NEF, et al. "Hyperbaric Oxygen and Multiple Sclerosis: Final Results of a Placebo-Controlled, Double-Blind Trial." *J Neurol Neurosurg Psychiatry* 1987;50:1402-1406; and Kindwall EP, McQuillen MP, Khatari BO, et al. "Treatment of Multiple Sclerosis with Hyperbaric Oxygen: Results of a National Registry." *Arch Neurol* 1991;48:195-199.

[4] National Institutes of Health. *Interim Report: Low-dose Oral Interferon Alpha as a Therapy for Human Immunodeficiency Virus Infection (HIV-1): Completed and Ongoing Clinical Trials*. April 1992.

[5] Koech DK, Obel AO, Minowada J, et al. "Low-Dose Oral Alpha-Interferon Therapy for Patients Seropositive for Human Immunodeficiency Virus Type-1 (HIV-l)." *Molecular Biotherapy* 1990;2:91-95.

[6] News Release. National Institute of Allergy and Infectious Diseases, National Institutes of Health. Executive Summary - AIDS Research Advisory Committee. March 31, 1992.

[7] "Another Day, Another Trial: A Commentary." *Treatment Issues: Gay Men's Health Crisis* 1994;8(4):1-2.

[8] Deyton LR. Letter to CPCRA Steering Committee, October 5, 1993. Dr. Deyton became Director, VA AIDS Service, in January 1998.

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5. Surrogate-Written Advance Directives

Introduction

The Subcommittee on Surrogate-Written Advance Directives was asked to consider whether surrogate decision-makers[1] should be permitted to write advance directives[2] for incompetent patients.[3] The primary charge was to determine whether such a policy would benefit the patient. Accordingly, the inquiry focused on two ethical issues: First, would such a policy increase the ability of the health care team and the surrogate to carry our the patient's wishes? Second, if the patient's wishes are not known, would such a policy better enable the surrogate and the health care team to act in the patient's best interest?

The question of whether surrogates should be permitted to write advance directives for incompetent patients has not been explored or debated in the bioethics literature. Further, very few states have enacted legislation pertaining to this issue.[4] Under VA policy, surrogates may make the decision to withhold or withdraw life-sustaining treatment for incompetent patients who are terminally ill. However, the policy does not address the extent to which surrogate decision-makers are permitted to make such decisions in advance. Surrogate instructions about life support are generally documented in the progress notes, but the patient's medical record is not routinely flagged to indicate the presence of these instructions.[5] The only exception is "Do Not Resuscitate" (DNR) orders.[6] Under VA policy, surrogates may consent to placement of a DNR order in the medical record of an incompetent patient who is terminally ill. The patient's DNR status is typically indicated on the outside of the medical record.

The current VA policy on advance directives[7] does not specifically state whether anyone other than a competent patient may execute a "VA Living Will", "Durable Power of Attorney for Health Care,"[8] or "Treatment Preferences Form." VA has historically interpreted this policy as permitting only the patient to execute an advance directive on his or her own behalf. When the proposal to allow surrogates to write advance directives on behalf of incompetent patients was debated before the VHA Bioethics Committee, members expressed widely divergent views. Some argued the proposed change would promote patient autonomy by allowing incompetent patients to exercise their right of self-determination through a surrogate. Others expressed grave concern that while such a policy might be clinically or economically expedient, it would not necessarily benefit the patient.[9] The substance of the debate is set forth below.

Discussion

Benefits of Allowing Surrogate Decision-Makers to Execute Advance Directives

The argument in favor of allowing a surrogate to execute an advance directive on behalf of an incompetent individual begins with the premise that, to the extent feasible, patients who lack decision-making capacity should be afforded the same rights and privileges as other VA patients. Allowing a surrogate to write an advance directive on behalf of an incompetent patient would further the goal of patient self-determination when the patient has expressed his or her wishes, but has not executed an advance directive form. A family member or guardian who is involved in the patient's care, and who knows what the patient would have wanted, could write an advance directive to that effect. Current VA policy concerning the withholding and withdrawal of life-sustaining treatment provides that the rights of patients "to direct the course of medical treatment *are not extinguished* by the lack of decision making capacity or by the fact that an advance directive. . .has not been previously executed." M-2, Part 1, Chapter 31, paragraph 31.06 (emphasis added). If a patient's right to direct the course of his or her medical treatment includes the right to make

certain decisions concerning future health care by an advance directive, then arguably it would be reasonable of VA to allow a patient to exercise that right through a surrogate.

VA policy expressly authorizes surrogates to make treatment decisions concerning life support for incompetent patients. The surrogate is responsible for making that decision based on his or her knowledge of the patient's wishes. In the absence of any reliable indication of what the patient would have wanted, the surrogate and the physician must decide what is in the patient's best interest. The criteria for making such a determination would not change if the surrogate were authorized to write an advance directive on the patient's behalf.

VA advance directives apply to limited situations, e.g., when the proposed treatment or procedure at issue involves life support. Even the VA Treatment Preferences form, which allows patients to give specific examples, e.g., "Life support may be discontinued if I am permanently unconscious," does not cover every contingency. The physician is required to get the surrogate's consent for any treatment or procedure related to the patient's ongoing medical care, including life support procedures not expressly covered in an advance directive. If there is a significant change in the patient's condition or new technology becomes available, the surrogate's prior treatment decisions may no longer apply.

When discussing treatment options for an incompetent patient who is terminally ill, the physician will often ask the surrogate about the use of life support procedures. If the physician is confident that the surrogate's response is based on reliable information about what the patient would have wanted, then the physician is obligated to comply with that decision. Except for DNR orders, surrogate instructions concerning the use of life support are not indicated on the face of the medical record. This increases the risk in an emergency setting that treatment will be initiated despite the surrogate's instructions to limit the use of extraordinary medical procedures. Although the surrogate may later request the withdrawal of life support, the patient's desire

not to undergo this type of procedure has been thwarted. One benefit of allowing a surrogate to execute an advance directive on behalf of the patient is that it would avoid circumstances where treatment is initiated contrary to the patient's wishes when the surrogate is not immediately available. An advance directive executed by the surrogate would ideally be indicated on the outside of the patient's medical record. Consequently, information provided by the surrogate about the patient's treatment preferences would be more accessible to the health care team.

Allowing surrogates to execute advance directives may encourage the physician and surrogate to discuss the question of life support before there is a need to make a specific treatment decision. Competent patients are encouraged to discuss their feelings about end-of-life decisions with their family members and physician well in advance. Similarly, surrogates should consider the question of life support before there is a need for this type of clinical intervention. Careful consideration of this subject before the surrogate has to decide to withhold or withdraw life support for a loved one is more likely to result in a decision consistent with the patient's wishes. A policy that permits surrogates to write advance directives may promote communication between the health care team and the surrogate about this sensitive subject. As a result, the surrogate is more likely to make a decision consistent with the patient's overall treatment goals and/or in the patient's best interest.

Potential Drawbacks to Allowing Surrogates to Execute Advance Directives

It is possible that the use of an advance directive may actually decrease, rather than increase, communication between the surrogate and the health care team. If the surrogate has prepared a written document detailing treatment preferences, the health care team may be tempted to rely on that document rather than contact the surrogate to discuss specific treatment issues. Such a practice may be convenient for the facility or for the surrogate, but it would not necessarily advance the patient's wishes or best interest. Advances in medical technology

may also alter the treatment scenario. Although the surrogate's decision may have been valid when the advance directive was written, the factual circumstances may have changed by the time the decision is implemented. In addition the patient's adaptation to his or her medical condition may have changed. The risk to the patient is that the health care team will implement a decision, based on outdated information, inconsistent with the patient's wishes or contrary to the patient's best interest. A "best interest" determination must be based on contemporaneous information.

In a typical informed consent discussion with the surrogate, the physician explains the effect of the proposed treatment or procedure given the patient's present condition. New information may cause the surrogate to rethink previous assumptions about what the patient would have wanted, or reconsider whether a proposed treatment is in the patient's best interest. Before implementing a decision to withhold or withdraw life support, the physician must be confident that the surrogate's decision is consistent with the patient's desires as indicated, e.g., by the patient's prior statements or religious philosophy. If there are no reliable indicators of the patient's wishes, the physician and surrogate must agree that the withholding or withdrawal of life support is in the patient's best interest. Their decision must be based on whatever information is available about the patient's subjective wishes. In addition, the physician and surrogate must consider the patient's diagnosis and prognosis and the nature and extent of the proposed treatment. This requires ongoing communication between the surrogate and the health care team. If the health care team relies solely on a written directive, its ability to gauge the accuracy or appropriateness of the surrogate's decision may be diminished. This circumstance lessens the opportunity of the health care team to assess the motivations for the surrogate's decision.

A different problem may result if a surrogate of higher priority comes forward after an advance directive has been executed on the patient's behalf. Problems may also develop if a subsequent surrogate is required to abide by decisions made by a previous surrogate. If that individual has died or relinquished his/her responsibilities as surrogate

some time ago, it may be difficult to determine the previous surrogate's rationale for making a particular treatment decision. This situation may be exacerbated if the subsequent surrogate has additional or conflicting information regarding the patient's wishes or best interest.

When a surrogate makes a decision on behalf of an incompetent patient, the surrogate is arguably acting as the agent of the patient. It is a well-established principle, under both common law and state law, that an agency relationship terminates with the death of the agent. A policy that allows a surrogate to dictate the course of the patient's medical treatment in a written directive that survives the surrogate's death may violate the basic principle of agency law noted above.

Conclusion

The committee strongly supports advance planning and coordination of decision-making between the surrogate and the health care team. The committee's discussion of surrogate-written advance directives focused on whether a policy that allows a surrogate to execute an advance directive on behalf of an incompetent patient would promote the ability of the health care team to either carry out the patient's known wishes or determine what is in the patient's best interest. The committee remains divided, however, on whether such a policy would promote the patient's wishes or best interest. The majority felt that the drawbacks outweighed the potential benefits. Furthermore, the novel nature of this issue, the absence of any discussion in the bioethics literature, and the limited scope of state legislation on the subject count against formalizing a VA policy on the issue at this time. The VHA Bioethics Committee expects to revisit the issue of surrogate-written advance directives in the future when existing policies on VA advance directives are revised.

Notes

1 **Surrogate decision-maker**: a person authorized under VA policy to make decisions on behalf of an incompetent patient.

2 **Advance directive**: specific oral or written statements made by a competent adult which provide direction as to that person's desires concerning the withholding or withdrawal of life-sustaining treatment (e.g., a living will or similar document) and/or specific written instructions as to who should make decisions regarding medical care in the event the individual is unable to do so, e.g., DPAHC (Durable Power of Attorney for Health Care).

3 **Incompetent patient**: an individual who lacks the capacity to formulate and/or communicate decisions concerning health care. This definition includes, but is not limited to, a person determined to be incompetent to make decisions concerning his or her person by a court.

4 As of January 1996, one state, Arkansas, allows surrogates to sign advance directives on behalf of minors or adults who lack the ability to make health care decisions. Three other states, Texas, New Mexico, and Louisiana, allow designated surrogates to complete advance directives on behalf of terminally ill minor children.

5 A survey of 15 VA medical facilities suggests that there is support for formalizing the process by which surrogates make decisions concerning life support for incompetent patients. Four of the facilities surveyed (Miami, Newington, Bedford, and Amarillo) use forms designed by their respective bioethics committees expressly for this purpose.

6 See VHA Manual M-2, Part 1, Chapter 30, "Do Not Resuscitate (DNR) Protocols."

7 See VHA Manual M-2, Part 1, Chapter 31, "Withholding and Withdrawal of Life-Sustaining Treatment."

8 Subcommittee members rejected the idea of allowing surrogates to

designate a health care agent under a DPAHC. If the surrogate or designated health care agent is unable or unwilling to make health care decisions for the patient, then the responsibility would fall to the next authorized surrogate under VA policy. See VHA Handbook 1004.1, "Informed Consent."

9 Three of the 15 VA medical facilities surveyed, Martinsburg, Portland, and Topeka,were strongly opposed to any policy change that would allow surrogates to write advance directives on behalf of incompetent patients.

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6. Ethical Issues in Long-Term Care

Executive Summary

Although there are many possible issues, we selected for detailed discussion in this report three areas of complex ethical issues that are unique to patient care in the long-term care setting. For the purposes of this report, long-term care includes inpatient units whose population is anticipated to reside there for more than three months, e.g., nursing homes, spinal cord injury units, psychiatric units. The committee intends its comments to be generalizable to any of these long-term care patient populations unless stated otherwise. Each of the three sections is followed by specific recommendations for health care providers. A bibliography is included to provide an overview of the literature in ethics in long-term care.

In the first section, we explore the definitions of competence and decision-making capacity, their use in everyday clinical parlance, ethical considerations in decision-making, and the impact of these considerations on issues of informed consent. Special concerns for cognitively-impaired patients are discussed and illustrated with case examples.

Next, this reports considers concerns in long-term care about appropriate use of mechanisms for advance care planning, issues of policy and patient preference for resuscitation and transfer, and the quality of dying, including relief of pain and suffering and demedicalization of the dying experience.

Finally, from the caregiver's perspective, we examine social and

institutional expectations surrounding the staff who care for the frail and elderly. A short case is used to demonstrate how long-term caregivers may find support in dealing with complex and emotion-laden clinical ethical issues. The analysis considers how sensitivity to cultural diversity affects patient/caregiver relationships and provides an overview of ethical principles and perspectives that may frame discussion of clinical ethical issues in long-term care.

Summary of Recommendations

1. Clinical evaluation of patients whose decision-making capacity is in question should include looking for a history of changes in emotional and cognitive states.
2. In the patient who exhibits recent memory loss, an earlier discussion with the provider about a treatment recommendation may not be remembered. The primary provider should determine whether inconsistencies are the result of caprice or cognitive impairment, versus inconsistencies that may be a result of truly altered preferences in a patient whose medical or social condition has changed.
3. Assessment of decision-making capacity should be carried out by the appropriate primary provider who is most familiar with the patient.
4. If the primary provider is uncertain whether the patient has adequate decision-making capacity, the appropriate specialist (e.g., psychiatrist, psychologist or behavioral neurologist) should be consulted to evaluate the patient.
5. Health care facilities should develop policies that promote advance care planning and decision-making while the patient is clinically stable and has decision-making capacity.
6. Caregivers and facilities should work to solve the logistical problems regarding implementation of advance directives that have become apparent since these documents have received more widespread use.

7. Long-term care units should establish explicit policies or clinical guidelines regarding resuscitation and transfer to acute care facilities, pain management, and comfort care for patients who are near the end of life.
8. Long-term care facilities should provide adequate clinical training and ongoing educational, social, and emotional support for caregivers who work with dying patients.
9. Caregivers should develop the skills to alleviate or ameliorate both physical and psychological suffering at the end of life, utilizing hospice care teams when appropriate.
10. Caregivers should be familiar with the cultural and spiritual aspects of dying that contribute to the overall quality of dying for individuals.
11. Ongoing education and training in ethical theory and moral decision-making should be provided for caregivers in long-term care settings.
12. Formal support groups for caregivers on long-term care units should be established to provide an opportunity for discussion of ethical issues that frequently arise in this setting.
13. A forum for discussion of ethical decisions should be provided for families of patients and caregivers in long-term care settings (family conferences or ethics advisory committee meetings).
14. A mechanism for resolution of ethical issues unique to the long-term care setting should be established at each VA facility.

Competence and Decision-Making Capacity

Competence is a legal term denoting the capacity to act on one's own behalf and to make decisions relevant to one's interests and welfare for which one can be legitimately judged accountable. The issue of an individual's competence may arise in regard to the capacity to manage one's own financial affairs, to stand trial, or to make health care decisions. An individual's competence may become compromised in certain clinical situations, either temporarily or permanently.[1]

Judicial Determinations of Competence

The law presumes that all adults are competent until specific evidence indicates otherwise. Determination that an individual is not competent is made only by a court or appropriate judicial authority. Most frequently, judicial assessment of competence arises in civil situations involving contractual agreements: disposal of property by sale, gift, or will; marriage; adoption; and divorce. In criminal matters, the issue of competence may arise with regard to one's capacities at the time a crime was committed, and whether one should be required to stand trial or be permitted to assist in one's own defense. A court may also determine that an individual lacks the capacity to make health care decisions and may, as part of that determination, appoint a legal guardian or a special guardian for health care to act as a surrogate if necessary.[2]

Decision-Making Capacity

For patients[3] in long-term care facilities, questions regarding decision-making capacity may arise and complicate many clinical situations.[4] In the everyday practice of medicine, the term decision-making capacity is often misused synonymously with the term competence.[5] In 1982, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research issued a report entitled "Making Health-Care Decisions."[6] Based on the findings of the President's Commission and the consensus of the clinical ethics literature, an adult who can meet the following criteria may be said to have decision-making capacity. Such an individual should be able to demonstrate:

1. the ability to understand the information presented,
2. the ability to appreciate the consequences of acting (or not acting) on that information with reference to one's own values and goals,
3. the ability to understand that choices are being offered and to deliberate among the choices,

4. the ability to make a consistent or stable choice which is not revoked or altered capriciously, and
5. the ability to communicate that choice.

The President's Commission noted the following:

"…society seeks to enhance their (those with limited capacity) well-being by protecting them from substantial harms (or loss of benefits) that could result from serious defects in their decision-making abilities."

"…a conclusion about a patient's decision-making capacity necessarily reflects a balancing of two important, sometimes competing objectives: to enhance a patient's well-being and to respect the person as a self-determining individual. Commentators have sometimes failed to recognize this balancing element, viewing 'capacity' or 'competence' as having intrinsic meaning apart from consideration of particular circumstances or situations…"

"...determinations of incapacity to participate in medical decision-making should reflect the balance of possibly competing interests."[7]

In the clinical setting, heath care providers make determinations regularly regarding the capacity of a given patient to make health care decisions.[8] Most often, if the patient is deemed unable to make that type of decision, the appropriate surrogate decision-maker is consulted. If the primary provider is uncertain about the patient's capacity, he/she may seek consultation by an appropriate professional who is qualified to evaluate decision-making capacity.[9] Such consultation may be useful to the primary provider who has ultimate responsibility for the patient's care. A judicial determination of incompetence and appointment of a guardian to make health care decisions is not required unless that patient has no designated or otherwise authorized surrogate.[10]

Ethical Considerations in Decision-Making

Informed, patient-centered decision-making is based on the ethical principles of autonomy and beneficence.[11] To make autonomous decisions, an individual must be able to develop a personal value

structure and use it to guide and evaluate his or her own decisions and those of others.[12] Health care providers respect autonomy by accepting the patient's ultimate decisional authority and working to promote autonomous decision-making. To that end, they should provide appropriate and relevant information, try to assure that the patient understands the information, avoid coercion, and implement the patient's choice.

Providers also have a professional obligation to act beneficently to promote and to protect the well-being of their patients. However, the patient is best qualified to identify what counts as good or beneficial in his/her individual circumstances. The provider is best qualified to identify options for the patient that may help him/her to achieve his/her goals.

A patient's refusal of recommended treatment is a commonly cited reason for questioning that patient's capacity for decision-making.[13] Conscientious providers may believe they are acting to promote the patient's well-being by protecting the patient against the consequences of a "poor" choice. However, this beneficent "protection" comes at the expense of the patient's autonomy or right to make a determination of what counts as "good" for oneself. The patient is entitled to choose from among the options presented and is not under an obligation to agree with the provider's recommendation.

It is the provider's responsibility to ensure that the patient is capable of making a choice and to provide an atmosphere for decision-making that promotes patient autonomy and well-being. A truly beneficent provider allows the patient to make decisions based on the patient's own value structure and to determine what counts as beneficial personally. This tension between respecting autonomy and acting beneficently is heightened when the patient may have limited or compromised capacity to make such decisions. An important challenge for the provider is to maintain an appropriate, morally justified balance between autonomy and beneficence.

Cognitive Impairment and Decision-Making Capacity

Mental disability alone should not disqualify a patient from health care decision-making unless there is specific evidence that decision-making capacity has been lost.[14] A person whose decision-making capacity is impaired may have a psychiatric (e.g., psychosis, neurosis, personality, or behavior), neurobehavioral (e.g. Alzheimer's or multi-infarct dementia), metabolic (e.g., endocrine encephalopathy) or developmental (e.g., mental retardation) disorder that affects cognitive or emotional functions to the extent that capacity for reasoning and judgment is significantly diminished. While capacity for decision-making may be impaired, these individuals may still be capable of making many decisions for themselves.[15] In addition, patients who have intermittent intervals of lucidity may be able to make some types of decisions in those lucid intervals and should not necessarily be considered incapable of making any decisions. For all cognitively impaired patients, the health care provider should carefully assess the patient's capacity and promote autonomous decision-making whenever possible.

Because of the complexity of cognitive and emotional deficiencies, and the waxing and waning nature of many of these disorders, careful assessment of capacity to make decisions requires expertise and a significant time investment on the part of the provider making the evaluation.[16] There is no simple, agreed-upon algorithm for quick assessment of a patient's decision-making capacity. In some cases, consultation should be sought from an appropriate specialist (e.g., psychiatrist, psychologist, behavioral neurologist). Particularly for patients whose cognitive or emotional state may vary considerably over time, an ongoing assessment by the consulting provider may identify periods of lucidity during which the patient may have the capacity to make decisions to guide treatment and indicate future preferences.

Case Example

A young schizophrenic, long estranged from his family with no guardian or conservator, is hospitalized for treatment of an acute psychotic episode. During that hospitalization, he develops symptoms of acute appendicitis. A surgeon is consulted and recommends an immediate operation, but refuses to operate on the patient until his family comes in to provide consent. The patient becomes angry, says his family hasn't seen him in years and would not care whether he lived or died. The patient also states that he understands he is very ill and may die if he does not have the surgery. He wants to sign the consent form for the procedure. He also believes the clinical staff are Martian and are wearing rubber masks to conceal their true origins. One might argue successfully that he is not competent for some tasks in the legal sense, but he does meet the criteria for having decision-making capacity in this particular clinical setting.

Sliding Scale of Decision-Making Capacity

Some authors have suggested that the criteria for determining decision-making capacity be flexible, tying the assessment of decision-making capacity to the patient's comprehension of the balance of risks and benefits associated with the decision. Drane and others have argued for a "sliding scale" as a reasonable way to enhance both the patient's liberty and well-being.[17] Using a sliding scale, stricter tests of capacity are employed when the risks of the proposed treatment or procedure pose serious dangers to the patient or when a refusal of recommended treatment may result in significant harm to the patient. While decision-making capacity is generally agreed to be a threshold determination, that threshold may slide up or down. As Drane says "…when the consequences flowing from patient decisions become more serious, competency standards for valid consent or refusal become more stringent." One potential weakness of this approach is that it may be misused in certain clinical situations as a justification for undermining respect for autonomy and promoting paternalism.

Case Example

Mrs. D., a WWII army nurse lived a fulfilling life until she was 60 years old when, in a single traumatic year, her husband died of lung cancer, her only grandchild was killed in a drive-by shooting, and her daughter committed suicide. Now at age 73, she presents with a history of several months of cough and blood-tinged sputum, which is diagnosed as bronchogenic carcinoma. Her thoracic surgeon recommends removal of the cancerous lung, but is concerned about whether Mrs. D. has adequate decision-making capacity to give consent.

A number of clinical specialists are consulted to evaluate Mrs. D.'s complex medical condition (emphysema, angina, hypertension, mild clinical depression, mild multi-infarct dementia) and the impact on her decision-making capacity. Mrs. D.'s decision-making capacity is threatened by a combination of clinical factors including depression, a sense of demoralization, mild dementia, and the adverse effects of polypharmacy on her cognitive function. Despite her cognitive impairment, the clinical staff believe she has a good understanding of the seriousness of her prognosis, the risks of the surgery, and the possible consequences of treatment versus no treatment. They feel she is capable of making an informed decision.

A clinical ethicist reviews the case, talks with Mrs. D., and concurs with the impression held by the clinical staff. After lengthy discussion with a supportive childhood friend, she tells her surgeon she would like to undergo surgery to have her lung removed.

Modified or Limited Guardianship

Modified or limited guardianship was originally devised to assist with the medical care needs of cognitively impaired adults who could often understand certain illnesses and the discomfort they caused, but could not comprehend the nature and/or consequences of particular treatment options. When such a patient needed diagnostic studies or treatment, the provider discussed the options with him/her in the presence of a "limited guardian," who would work with the patient by

going over the details in very simplified terms and by assisting the patient in making his/her own decision when the patient was capable of doing so.

On the occasions when the patient is unable to make the decision for himself/herself, the limited guardian provides consent based on knowledge of the patient acquired over time: his/her values, goals, abilities and the nature of the particular clinical problem. In VHA, only an authorized surrogate may make health care decisions for a patient who does not have the capacity to make decisions for himself/herself.[18] It may be helpful in cognitively impaired patients to have the authorized surrogate decision-maker act as a "limited guardian" to help preserve and maximize patient autonomy.

Recommendations

1. Clinical evaluation of patients whose decision-making capacity is in question should especially include looking for a history of changes in emotional and cognitive states. With advances in understanding of brain-behavior relations, neurobehavioral as well as psychiatric examinations may be conducted. Evaluation should include analysis of the five critical concepts regarding patients abilities, as noted earlier in this report. A thorough clinical interview with the patient, including a complete mental status examination, is an essential part of the evaluation process. For patients who have intermittent periods of lucidity, repeated evaluations over time may be necessary to capture their greatest decision-making capacities.
2. When the patient exhibits recent memory loss, he/she may not recall an earlier discussion with the provider about a treatment recommendation. In this case, repeated discussions may reveal that the patient's preferences remain consistent with the original treatment plan. If the patient's preferences are now inconsistent with previous decisions, careful evaluation of decision-making capacity should be undertaken. While some inconsistencies may be the result of caprice or cognitive impairment, others may be a result of truly altered preferences in a patient whose medical or social condition has changed.

3. Ideally in the long-term care setting, assessment of decision-making capacity should include the participation of the appropriate primary provider who is familiar with the patient. Assessments should be made in a quiet room with as few distractions as possible, paying careful attention to the patient's level of alertness, level of attention, attention span, eye contact, and body language. The provider should speak the patient's native language (vernacular) and avoid the use of medical jargon.

   In many cases, the patient may be made more comfortable or be reassured by the presence of a trusted friend or the individual he/she has named a surrogate decision-maker. (The latter would not be acting as surrogate since the patient still has decision-making capacity.) Caution should be exercised lest there be an element of implied or subtle coercion by having the surrogate present.

4. If the primary provider is uncertain whether the patient has adequate decision-making capacity, the appropriate specialist (e.g., psychiatrist, psychologist, or behavioral neurologist) should be consulted to evaluate the patient.

Advance Care Planning, Resuscitation, and Quality of Dying

Advance Care Planning

Advance care planning is a deliberative process that permits individuals to indicate their preferences for future medical care in the event that they are unable to make decisions for themselves at that time. In this planning process, individuals clarify their personal health care goals and evaluate the benefits and burdens of future treatment. They should try to choose treatments most consistent with their values and goals. In the long-term care setting, the responsibility of health care providers to assist patients in evaluating their treatment options often includes advance care planning, e.g., completion of advance directives, designation of surrogate decision-makers, and

consideration of issues surrounding dying and resuscitation. The obligations of the providers to respect patient autonomy and act beneficently are particularly important in helping patients make decisions about life-sustaining treatments.[19]

Many patients in long-term care facilities are able to work with their providers and families to make thoughtful advance care plans and execute written advance directives. However, a number of long-term care patients are admitted with compromised mental or communication abilities. Some of these individuals, after careful evaluation, may be found to be capable of making some or all health care decisions for themselves, e.g., patients having spinal cord injuries, certain psychiatric disorders, or mild dementia. Health care staff and families should work with these patients to engage them in the planning process and encourage them to make advance care plans when possible. Other patients may have fluctuating capacity to engage in this process and providers must work especially hard with this group to engage them as far as possible in planning for their own care.[20] Still another group of patients may have insufficient decision-making capacity to participate meaningfully in advance care planning or in the consent process required to execute written advance directives. Their authorized surrogate decision-maker will make their health care decisions.[21]

The Role of Surrogates for Patients Without Decision-Making Capacity and Who Have Not Executed an Advance Directive

Patients who lack decision-making capacity and who have no written advance directive must have their health care decisions made by an authorized surrogate. The health care staff needs to identify the appropriate person to act as surrogate for the patient and ascertain whether the surrogate is familiar with the patient's values and goals.[22] If the patient has not discussed preferences with the surrogate, but has shared them informally with the health care staff, it is important to share that information with the surrogate as well. Surrogates participate in the decision-making process at the time particular care plans or diagnostic or therapeutic treatments are recommended by the

provider. VHA policy does not currently permit surrogates to execute written advance directives for patients without decision-making capacity.[23]

The decision-making process for the surrogate will reflect his/her familiarity with the patient's preferences. As in all health care decision-making, the process should promote and preserve the patient's autonomy. When possible, the authorized surrogate should use "substituted judgment" – i.e., the surrogate should attempt to make the decision that the patient would have made if he/she still had the capacity to do so. Without knowledge of the patient's preferences or values, the ability of a surrogate to make decisions using substituted judgment is compromised. In that event, the surrogate has to make decisions based on his opinion of what would be in the patient's best interests in the context of the patient's current quality of life.[24]

Reviewing Patients' Preferences and Advance Directives

When residents of long-term care facilities have executed written advance directives, health care providers should not assume that these are necessarily fixed preferences. Health care staff should initiate discussions with each patient to explore whether his/her preferences or health care goals have altered whenever there are significant changes in the patient's health or social circumstances. If appropriate, any previously executed advance directives should be updated to reflect any changes in the patient's preferences. When the patient's course has been stable, advance directives should be re-examined with the patient at regular intervals in a routine review and recorded in the patient's medical record. One important goal of advance planning is to promote the patient's participation in decision-making. The responsibility for periodic re-evaluation of the patient's preferences and advance directives is an important one and should be a regular part of the primary care of the patient.

Health care facilities should determine as a matter of policy which health care staff member(s) will be responsible for this periodic review of advance directives, as well as ensure appropriate and accessible

documentation of the review. Regardless of which staff member is responsible for the review, the primary care physician should be familiar with the patient's current directive. Mechanisms should be developed for communicating the existence and content of the patient's advance directive to all providers in the long-term care facility, as well as the providers in acute care settings for those patients who are transferred.

Logistical Issues

Finally, the logistics of having a properly executed advance directive in the location where it is needed and when it is needed are often complex. This logistical challenge requires effective, consistently followed, administrative procedures and careful education and planning for the staff, patient, and family.

Resuscitation and Transfer

All long-term care facilities should strive to provide the best possible comfort care to all patients regardless of the resuscitation or transfer status of the patient. As part of their mission statement, long-term care facilities ought to establish and make explicit clear policies regarding resuscitation and transfer of patients who have become acutely ill. All parties who have a stake in these policies should participate in their development. In addition, resuscitation and transfer policies should articulate fair mechanisms to manage disagreements between patients and their families and health care staff. Since individuals admitted to long-term care facilities may be experiencing an adjustment reaction to loss of function and independence, their expressed preferences should be carefully assessed and any evidence of clinical depression should be thoroughly evaluated, particularly if their preference is for no resuscitation or transfer. As with all advance care planning, preferences should be regularly reviewed.[25]

Two major issues that may arise in long-term care facilities are 1) whether cardiopulmonary resuscitation (CPR) should be attempted in the event of a cardiac arrest, and 2) whether the resident should be transferred to an acute care facility for an acute deterioration in health status. Optimally, these issues should be discussed with the patient and

his/her family in the context of advance care planning when the patient is clinically stable. It is important not to delay discussing issues of resuscitation with patients unless there is good cause to do so. Due to the frailty of many patients in long-term care facilities, delay may result in a lost opportunity for patient input and the health care staff must then rely on the judgment of surrogates who are often uncomfortable with this type of decision or unfamiliar with the patient's preferences.

Use of CPR in Long-Term Care Facilities

Long-term care facility policies should consider the appropriateness of CPR under specific clinical conditions. CPR was developed originally to reverse intra-operative cardiac arrest or sudden, unexpected arrest in young healthy individuals, and in victims of drowning and electrocution. Over time, the use of CPR has been extended to many other clinical situations. There is a growing literature that characterizes the circumstances under which CPR is considered to be medically inappropriate or futile (e.g., when patients are dying of a terminal condition, multi-organ failure, when CPR is initiated too late.)[26] Thus, for many patients in long-term care facilities, initiation of CPR may be inappropriate because the likelihood of success or restoration to a good state of health is very low or non-existent.[27]

CPR may not be compatible with the goals of care for some patients in a long-term care facility. Maintaining quality of life and maximal independence in a safe environment is different from instituting advanced cardiac life support efforts to simply prolong life.[28] In some circumstances, such as with spinal cord injury patients or patients with psychiatric diagnoses, CPR may be an appropriate treatment option. For older, frail nursing home patients, the philosophy of care of the facility and the health care goals of the patient may not include CPR, as it connotes acceptance of "rescue medicine." While it is commonplace for CPR to be the default option on all patients without a do-not-resuscitate order who have a cardiopulmonary arrest, long-term care facilities may wish to reassess their policies on resuscitation to see if this is appropriate and consistent with both the facilities'

philosophy of care and patient preferences. If a facility considers CPR to be an inappropriate treatment option for some patients (i.e., it is not the default option), this should be made explicit to all patients and their families prior to or at the time of admission. This offers patients and their families an opportunity to discuss the facility's philosophy of care and indicate their preferences regarding care at the outset.

Do-Not-Hospitalize (Transfer) Orders

While most health care providers are familiar with Do-Not-Resuscitate orders, few facilities provide an option of Do-Not-Hospitalize or have as an explicit policy that patients may choose in advance not to be transferred to an acute care facility and have an order written to that effect. Offering this as an option to patients may provide a means of respecting patient values and more appropriately assist them in achieving their health care goals. For example, consider the patient who has a DNR order, becomes febrile and obtunded with labored breathing, and is transferred to an acute care facility with a probable diagnosis of pneumonia. In the intensive care unit the pneumonia is aggressively treated, but unfortunately the patient arrests and is not resuscitated (DNR order). This patient might have preferred the option of choosing to reside in a facility that would agree in advance not to transfer for acute deteriorations. Of course, facilities that offer Do-Not-Hospitalize orders as an option must be able to provide adequate care to patients to preserve their comfort and dignity in the event of an acute deterioration.

Quality of Dying

Quality of dying issues are a common concern in long-term care facilities providing care to elderly or dying patients.[29] The issues surrounding quality of dying may emerge gradually as a patient inexorably nears the end of life, allowing ample time for providers, patients, and families to plan for and participate in the dying process. Occasionally these issues may present themselves unexpectedly as a patient suddenly deteriorates. To promote a quality of dying that fosters peacefulness and dignity for all patients, long-term care units should work to articulate their mission or philosophy of care.[30]

Nursing Home Care Units (NHCUs) should develop explicit policies regarding care options for dying patients based on their philosophy of care and also within the context of the overall mission of the health care facility in which the NHCU is located. Occasionally, limits may have to be placed on patient and family autonomy when the patient's individual health care preferences or requests for specific treatments are outside the scope of the health care facility's mission. However, every effort should be made to develop care plans for dying patients that reflect and respect the values and preferences of the individual patient. In the NHCU, as in any other health care setting, providers should allow the patient to determine what counts as beneficial for himself/herself and to respect his/her choices.

In consideration of quality of dying issues, providers, other caregivers, and health care facilities may draw upon several ethical approaches for insight.[31] The justice or fairness of broad allocation decisions generally forms the framework of operationalizing the facility's overall health care mission.[32] On an individual level, the ethical principles of autonomy and beneficence form the basis of most personal health care decision-making in the United States. If health care decisions for individuals are made in the setting of a facility that has already reached broad operational decisions about the limits of patient autonomy and what constitutes beneficial care for some patients, then providers need not serve as health care resource gatekeepers and may function primarily as patients' advocates. Health care providers may utilize an ethic of care to view the concerns surrounding the dying patient from the perspective of the patient and his/her personal relationships, providing a highly individualized framework for the dying process. Virtue theory, for example, reminds providers that compassion and prudence can come together in a common sense approach to patient care.[33] Providers and other caregivers should draw on these ethical theories or perspectives to assist them in de-medicalizing the dying process and promoting a dignified, respectful, comfortable death.

Pain and Suffering

When caring for patients who are near the end of their lives, a primary concern is attention to comfort measures in order to relieve pain and suffering, to maintain personal functioning whenever possible, and to emphasize quality of life over quantity of life. Some NHCUs may choose to utilize a hospice care team as consultants whose main function is support of the patient through the dying process, attending to both physical and psychological needs. In VHA, these teams also provide pain management consultation to deal with specific issues of physical pain.[34] Clinical guidelines for "comfort measures only" may assist caregivers in appropriately caring for dying patients. For example, promotion of the patient's comfort might include limits on the use of artificial feeding devices, treatment of fevers with antipyretics rather than aggressive medical care, and maintaining cleanliness and moisture of the patient's skin. Caregivers should encourage family members to assist the patient through this difficult process.

Some caregivers find it useful to distinguish the more general concept of suffering from physical pain. Suffering may refer to physical, emotional, or spiritual symptoms. In the vast majority of dying patients, pain control is achievable using a full complement of pain control agents. Other physical symptoms that may cause suffering might include shortness of breath, weakness, gastrointestinal discomfort, and sleep disturbances. Psychological issues affecting the quality of dying may also need specific recognition and attention by caregivers to assist the patient in coping with his/her approaching death. Dying patients may be anxious or depressed, and they may be dealing with feelings of hopelessness, worthlessness, fear and apprehension. They may need help in coping with the enormous task of saying goodbye to family and friends and dealing with an overwhelming sense of loss. The long-term care facility should provide adequate training to its staff to recognize and manage these symptoms to ensure a high quality of support and care for the dying patient. Caregivers will also benefit from ongoing support for themselves in dealing with the emotional toll and special stresses inherent in caring for the dying patient.

For most patients, dying is a process. The care team should develop its care plan with regard to the overall dying process and not be inappropriately diverted from this plan by isolated medical events that may occur during or as part of the process. Prolongation of the process through some medical treatment options may not be beneficial to a patient. For example, a patient may fail to feed oneself or refuse feeding because he/she is far along in the dying process. This may be an event which could be anticipated and does not necessarily require intervention with artificial feeding devices. It may require, however, initiation of additional specific comfort measures. The care team should refer back to the health care goals as indicated in the care plan for the individual patient before making decisions about specific medical events in the course of care.[35]

A Caring Perspective

Until fairly recently in most Western societies, people have died at home either from a recognizable medical cause or from an unrecognizable but natural cause linked to the frailties of advanced age.[36] The experience of many caregivers is that most patients would still express a preference for dying at home if given the choice.[37] However, this is not possible for many patients. The nature of illness and related treatment or care may make it difficult for patients to remain at home and be cared for appropriately. The societal trend from extended to nuclear to single parent families and the geographic dispersion of family members may leave the patient with no family member(s) available to assist in his/her daily care. It may also be the case that otherwise available family members may not wish to care for a dying relative in their home. For example, many family members may have no previous close experience with death and may fear the actual circumstances surrounding the death itself or may not wish to have memories of a death occurring in a setting where they will continue to reside.

When patients die at home, the process may be accompanied by meaningful ritual and social interactions as friends and relatives gather around to say goodbye and perhaps to share memories or reflect on the

life of the one who is passing. These important rituals surrounding the dying person are often attenuated or may be missing in long-term care facilities. The NHCU can promote attention to these rituals by providing, for example, patient and family support groups. Such support groups may be able to offer some of the missing interactions necessary to bring social meaning to the remaining life and the death of these patients. Caregivers in any long-term care facility, and especially those taking care of dying patients, may develop a closer, more family-like relationship with the patient and the care plan may reflect this changed perspective. Care plans may be developed from a caring perspective. Caring or the care perspective is an emerging ethical perspective that provides a useful context for describing these complex caregiver/patient issues and has been discussed primarily in the nursing literature.[38]

Spiritual and pastoral caregivers are essential partners in the care of dying patients and are part of VHA hospice care teams. Caregivers should take the time to explore with the patient his/her perspective on spirituality and afterlife as part of the initial assessment. Often patients who have not been active members of an organized religion become interested in spiritual issues as they approach the end of their life. Pastoral caregivers may enhance the quality of the dying process and increase the comfort, both temporal and spiritual, provided the patient. They also may be a valuable resource to other members of the facility staff and the patient's family.[39]

Recommendations

1. Health care facilities should develop policies that promote advance care planning and decision-making while the patient has decision-making capacity and is in stable clinical circumstances. Care plans should promote patient autonomy and enhancement of the quality of life for all patients, especially those who are dying. Family members should be involved in the planning process whenever possible.
2. Caregivers and facilities should work to solve the logistical problems regarding implementation of advance directives that have become apparent since these documents have received more

widespread use. This is particularly important for patients who are transferred from a long-term to an acute care facility. Facilities in VHA should strive to share their experiences with these problems and innovative solutions which they have developed.

3. Long-term care units should establish explicit policies or clinical guidelines regarding resuscitation and transfer to acute care facilities, pain management, and comfort care for patients who are near the end of life. These policies should be carefully explained and discussed with patients and their families. Care plans for individual patients should reflect thoughtful consideration of their health care goals, as well as a realistic assessment of their clinical condition. Long-term care facilities should consider a Do-Not-Hospitalize option for some patients when appropriate.

4. Caregivers should become keen student-observers of the dying process and ask patients, their own family members, and fellow staff about their own personal and clinical experiences. This open discussion may help caregivers become more comfortable with the dying process and more empathetic to the needs of dying patients and their families. Long-term care facilities should provide adequate clinical training and ongoing educational, social, and emotional support for caregivers who work with dying patients.

5. Caregivers should develop the skills to alleviate or ameliorate both physical and psychological suffering at the end of life. Consultation with appropriate specialists or comfort care teams should be utilized to maximize patient comfort and the quality of dying.

6. Caregivers should be familiar with the social and spiritual aspects of dying that contribute to the overall quality of dying for individuals. They should strive to appreciate the cultural and religious backgrounds of their patients to better promote a peaceful, comfortable, and respectful death.

The Caregiver's Perspective

Caregiver Support: Introduction to the Concept

Caregivers in long-term care may include the patient's family and significant others, volunteers, and health care providers caring for the patient. This section will focus on the support of the health care provider who is on the staff of a long-term care unit or facility and is involved in the care of patients on the unit. The staff who are most often faced with clinical ethical issues and decisions in long-term care are physicians, nurses, social workers, rehabilitation therapists, chaplains, and nurse assistants.

Unique Attributes of Long-Term Care Settings

The need for caregiver support in long-term care settings reflects the special attributes of the patients and the clinical setting. These patients include individuals who may be frail, elderly, and/or chronically disabled from medical or psychiatric disorders or both. (This discussion excludes from consideration those patients who are in a nursing home or spinal cord injury unit for rehabilitation with plans for discharge to home.) Many individuals in our society, including health care providers, have difficulty confronting and accepting advanced age and frailty for themselves and for others. Arriving at any consensus about what constitutes quality of life for this chronically disabled, institutionalized patient population is difficult. While much attention has been given by VHA to the training of staff and students in the care of elderly and chronically ill patients, continued support for the health care provider in long-term care is important. Ongoing education and training activities and use of support groups are examples of initiatives that may assist staff in dealing with difficult situations arising in long-term care.[40]

Long-term care settings differ greatly from acute care settings in ways that affect caregiver attitudes about their patients. Use of medical technology is more limited, and patients' medical problems are often more disabling and less reversible. Patient lengths of stay are longer and

often indefinite. The relationships between patients and staff often become close and personal, developing over time and often lasting several months or even years. Staff frequently become surrogate family for those patients who have no family involved in their daily lives. Collopy summarizes some of the ethical issues arising out of these relationships in this way: "Daily personal care shapes the ethical environment of a long-term care unit for staff providing the hands-on care. For the patients themselves, this care is liable to carry intensely personal relational meaning. On both sides of these relationships, problems can develop around issues of choice and control, dignity and competency, modes of authority and accommodation."[41] Caregivers in long-term care need a structured forum in which to discuss the differences between responsibilities in familial relationships versus those in patient-caregiver relationships. A formal support group or ethics committee meeting devoted to the unique issues in long-term care settings may be an appropriate forum for these discussions.

Social and Institutional Perceptions of Long-Term Care

Society's perceptions of long-term care, as well as the health care institution's corporate perception of institutional long-term care, have significant impact on caregiver morale. The cultural view of nursing homes as grim keepers of the elderly seems still to prevail, even though much of it is based on past history rather than current reality, and on worst-case examples rather than more typical ones.[42] Caregivers may feel their work is undervalued by society. VHA's long-term care units and caregivers may be less affected by these negative perceptions than other long-term care facilities. VHA units are a well-recognized component of a large, comprehensive health care system required to meet the high standards prescribed by a single accreditation organization. The staff are well-trained in interdisciplinary primary care for long-term care patients. While well-respected in VHA, caregivers may still feel they receive less recognition and respect for their work from the community at large.

Literature about the health care institution's corporate perceptions of long-term care units is meager, but the value and expense of such care has been widely debated. At a time when fiscal resources are

limited and the demands of the expanding aged population on the health care system (both VHA and community) are projected to become even greater, debates on the high cost of institutional long-term care versus less costly community-based care are frequently heard. Decisions on resource allocation are being made at the corporate level of every health care institution.[43] The ethical issues related to these decisions should be discussed along with the fiscal issues. Caregivers in long-term care settings who have generally been strong advocates of elderly and disabled patients may find it beneficial to broaden their knowledge of ethical issues in resource allocation decision-making and become active participants in allocation decisions at social and institutional levels.

Ethical Issues Confronted by Caregivers

There currently is a limited but growing literature specifically relating to ethical issues in long-term care settings.[44] Collopy notes that in the world of bioethics, long-term care has lived something of a marginal existence, cutting its ethics from the cloth of acute care, largely from issues that cluster around autonomy, e.g., patient self-determination, medical decision-making, informed consent, and advance directives.[45] Two areas that are identified in the literature and important for consideration by caregivers are discussed below.[46]

Conflict Arising When a Patient Refuses Nutrition

It is recognized that in the long-term care setting, a personal as well as a professional relationship develops between the patient and the caregiver based on their long-term association. As a result caregivers may be particularly troubled when a patient in their care requests withholding or withdrawal of treatment that will result in the patient's death. One of the most difficult situations for staff to deal with arises when a long-term care patient who has decision-making capacity decides that the time has come for him/her to die and refuses to eat or be fed.[47] Several issues arise in such situations, including respect for the patient's autonomy versus beneficence (professional responsibility to protect the patient's welfare), the question of whether the patient's

refusal of nutrition clearly communicates an informed decision about his/her care, and conflicting personal, professional, and institutional values.[48]

Caregivers' discomfort with these requests may be ameliorated by consideration of four issues. First, respect for patient autonomy requires caregivers to accept the competent patient's decisions regarding treatment. Second, careful discussion with the patient may reveal the basis for his/her decisions, e.g., a patient's religious views or family financial concerns. Third, judicial rulings support the right of patients to accept or reject treatment.[49] Finally, many medical experts involved in palliative care believe that the withholding or withdrawal of artificial hydration and nutrition reduces suffering.[50] This occurs by decreasing pulmonary secretions, reducing incontinence, and increasing a patient's pain threshold.

Although careful discussions with the patient, family, and ethics consultants and reflection from legal, religious, and philosophical perspectives may be extremely useful, caregivers who have provided high-quality and personal care over several months or years to a patient in a long-term care unit may still find it difficult to watch the patient slowly deteriorate and slip into death. Therefore, continuing support for the staff caring for these patients, as well as the family and significant others of the patient, is also critical.

Diversity of Cultures and Values

In the community long-term care setting, there is increasing recognition of ethical issues arising from the diversity of cultural perspectives, i.e., multiculturalism for nursing home administrators, ethicists, and ethics committees.[51] Although the VHA long-term care patient population differs in some respects from that in the private sector, notably in gender, the distribution of ethnic backgrounds, race, and religions is usually similar to the patient population in community long-term care facilities. In addition, staffing in VHA's long-term care units is as diverse as that in private sector facilities. Conflicts may arise when the cultural background of patients is different from caregivers

because situations are viewed from different culturally-based ethical perspectives.[52]

For example, one patient's cultural tradition values decision-making by family consensus versus the individual alone for all important life situations, including those related to health care. In a long-term care unit where patient autonomy in decision-making is highly valued and encouraged by the staff, a conflict between the patient, his/her family, and the staff over the meaning of autonomy may arise. A second example involves the impact of differences in religious beliefs. These differences may be more pronounced in the long-term care setting because of the amount of time that patients and staff are together in the long-term care setting. Strong disagreements over privacy, autonomy, and fairness may emerge when one patient, because of his/her strong moral beliefs, is offended by programs watched by his/her roommate on television. Sensitivity to and respect for the cultural beliefs and values of patients and staff is a first step in dealing with differences that create conflict among staff and patient. In some situations, no conclusive resolution will be possible. As Boyle noted: "Whether the clash of values is created by religion, ethnicity, race or gender, the incommensurability of the values will lead to an impasse at times. Nevertheless, the process of moral struggle is not merely to arrive at a clinical solution. Those who struggle to split the difference honor others and in doing so become more human."[53]

Ethical Principles as Guidance for Caregivers

The long-term care setting provides an opportunity, as well as a challenge, for caregivers to foster a relationship with each patient that considers the patient as an individual and in the context of family and community. Community for these patients includes the present environment of other patients and staff in the long-term care unit and the past social environment in which the patients resided. Caregivers in the long-term care setting frequently consider a broad range of issues with patients and their families, including patient-caregiver relationships, the quality of everyday living in a long-term care setting, decisions related to medical care, and the quality of dying. Three ethical

principles that may be used to guide these important discussions are autonomy, beneficence, and justice.[54]

Autonomy and beneficence were discussed earlier in this report as they relate to health care decision-making. In that context, autonomy is patient focused and beneficence is caregiver focused. Examples were given where tensions may arise between respect for patient autonomy and the caregiver acting beneficently. In these situations the importance that the caregiver maintain an appropriate balance between these two ethical principles was emphasized. The ethical principle of justice frames most discussions about equitable distribution of resources. In these situations, the patient's decisions regarding daily living and health care and respect for autonomy may need to be tempered with justice for the entire community of patients in the long-term care unit. Concerns about justice and the effects of a patient's decisions also may be relevant in consideration of burdens imposed on the patient's family.[55]

The care ethic is an emerging ethical perspective that may have broad applicability in the long-term care setting where relationships between patients, patients and caregivers, and among patients, families and caregivers are critical to decision-making and resolution of conflicts.[56] The care ethic is grounded in the assumption that self and others are interdependent. An individual's response to situations is viewed as arising from a knowledge of and respect for another individual or individuals. The care perspective has been contrasted with the ethical principle of justice, where caring encompasses feelings and practical reasoning in moral decisions and justice is focused on thinking and theoretical reasoning. In situations that arise in the long-term care setting where moral decisions need to be made, the care perspective does not necessarily negate the principle of justice, but focuses attention on different dimensions of the situation. Since the issues in long-term care are complex and involve many caregivers of various backgrounds helping patients and their families make profound health care decisions, consideration of all ethical perspectives could enhance the process.

Recommendations

1. Ongoing education and training in clinical ethical theory and moral decision-making should be provided for caregivers in long-term care settings.
2. Formal support groups for caregivers on long-term care units should be established to provide an opportunity for discussion of ethical issues that frequently arise in this setting. These support groups may provide an opportunity to work through frequently emotion-laden issues for caregivers with peers who share the same concerns.
3. A forum for discussion of ethical decisions should be provided for families of patients and caregivers in long-term care settings. Appropriate forums may be family conferences or ethics advisory committee meetings.
4. A service for resolution of ethical issues unique to the long-term care setting should be established at each VA facility. The facility ethics advisory committee could assume this as one of their specific responsibilities. Inclusion of long-term care staff on the ethics advisory committee might facilitate the establishment of this type of service.

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Joint Commission on the Accreditation of Health Organizations (JCAHO) and others, reflecting an awareness of the home-like status of the facility for the individual. Individuals residing in other long-term care facilities who are spinal cord injured, terminally ill, or undergoing rehabilitation are more appropriately referred to as patients. For the purposes of this report, we will use only the term patient to refer to all of these groups of individuals.

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[10] VHA Informed Consent Policy can be found in VHA Handbook 1004.1/1, 12/23/97.

[11] For a discussion of the ethical principles of autonomy and beneficence see Beauchamp TL, Childress JF. *Principles of Biomedical Ethics*. New York: Oxford University Press, 1994. A discussion of these principles as they relate to competence is found in White BC. "Ethical Foundations of Competence to Consent," in *Competence to Consent*:13-43. Also see Kane R. "Ethics and Long-Term Care—Everyday Considerations," in *Clinics in Geriatric Medicine* 1994; 10:489-499.

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19 VHA policy on Advance Directives may be found in VHA Handbook 1004.2, "Advance Health Care Planning." In VHA, the term advance directive includes Durable Power of Attorney for Health Care, Living Will, and Treatment Preferences Form. DNR orders, while a form of advance planning are not considered an advance directive, but a treatment decision. Policy regarding DNR orders is found in the VHA Manual, Chapter 30, "Do-Not-Resuscitate," June 21, 1994. Some general articles on advance care planning include: Schneiderman LJ, Arras JD. "Counseling Patients to Counsel Physicians on Future Care in the Event of Patient Incompetence." *Ann Intern Med* 1985;102:693-698; Caralis PV, Davis B, Wright K, et al. "The Influence of Ethnicity and Race on Attitudes Toward Advance Directives, Life-Prolonging Treatments

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[23] VHA policy as set out in Chapter 30, "DNR Protocols," does permit surrogates to agree to a Do-Not-Resuscitate order since "the entry of a DNR order is essentially a question regarding treatment." For a discussion of the ethical issues arising in advance directives written by surrogates see the VHA Bioethics Committee Report on "Surrogate-Written Advance Directives" in this volume.

[24] For a more complete discussion of these terms see Brock and Buchanan, *Deciding for Others*.

[25] See VHA policy on resuscitation in Chapter 30. Also see LaPuma J, Orentlicher D, Moss RJ. "Advance Directives on Admission: Clinical Implications and Analysis of the Patient Self Determination Act of 1990." *JAMA* 1991;266(3):402-405; and Bedell SE, Delbanco TL. "Choices About Cardiopulmonary Resuscitation in the Hospital: When Do Physicians Talk with Patients?" *N Engl J Med* 1984;310:1089-1093.

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"Bibliography of Bioethics" is an ongoing project of the Kennedy Institute of Ethics that provides a comprehensive cross-disciplinary bibliography of current English-language bioethics materials. Citations are presented in both a Subject Index and an Author Index. In the Subject Index, related keywords are provided with each citation and some also include brief abstracts. Twenty volumes have been published to date and new volumes are published annually.

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7. Physician-Assisted Suicide

Charge

The VHA Bioethics Committee was charged to study the implications of permitting physician-assisted suicide (PAS) within the Veterans Health Administration (VHA), in anticipation of the future probability that PAS becomes legal in some jurisdictions.

Definitions[1]

Physician-assisted suicide is a physician's act of providing medical means for suicide, upon request, to a patient who is physically capable of committing suicide and who subsequently acts to carry out the suicide on his or her own using those means. In PAS, the physician's act is a necessary but not sufficient condition for the patient's suicide. An example of PAS is a physician prescribing an ample quantity of barbiturate capsules and instructing a patient on their dosage and route of administration to complete a successful suicide at a later date. Physicians who simply respond to patients' request for PAS by telling them books have been written on how to commit suicide are not performing PAS. Because this information is widely available, the physician's act is not a necessary component for the suicide. Similarly, physicians who warn patients that taking excessive amounts of a prescribed drug may be harmful are not performing PAS because providing cautionary information on drug overdosage is ordinary medical practice. PAS is distinguished from voluntary active euthanasia, withholding or withdrawing life-sustaining therapy that a patient has refused, and providing palliative care to a dying patient in the following ways.

Voluntary active euthanasia (VAE) is the physician's act to kill a patient, at the patient's request, by employing an action that is both necessary and sufficient for the patient's death. In VAE, the patient's underlying condition is not a necessary factor for the death. An example of VAE is a physician who administers a lethal injection to a patient at the patient's request immediately causing the patient's death. VAE is compassionate killing of the patient at the patient's request.

Withholding or withdrawing life-sustaining therapy that has been refused by a competent patient or the proxy of an incompetent patient in the past has been called "voluntary passive euthanasia." The latter term is misleading and should be abandoned. Withholding or withdrawing therapy at a patient's refusal is not euthanizing a patient because the patient is dying of the underlying disease. Withdrawing or withholding life-sustaining therapy refused by the patient has been termed more correctly "allowing to die." Here, in the absence of validly refused treatment, the patient's underlying disease is a necessary and sufficient cause of death.

Palliative care of the dying patient includes care directed toward the relief of pain and other causes of suffering.[2] Examples of palliative care are the judicious prescription of morphine and benzodiazepines to a dying patient. Physicians have a duty to provide dying patients palliative care to the best of their ability. If properly ordered and administered, palliative care unintentionally produces an acceleration of the moment of death, this "double effect" is not considered PAS or VAE. Rather, it is simply the price of providing adequate analgesia and comfort care.

Physician-aid-in-dying is a term that has been used to refer to the whole gamut of physician behaviors in the management of the dying patient. The term should be abandoned because it may encompass all of the above different acts and is inherently ambiguous and misleading.

Presumptions

Much of the public interest in legalizing PAS results from the common public perception that contemporary physicians fail to provide adequate comfort care to dying patients and that dying patients are suffering unnecessarily as a result. Many patients similarly fear that physicians will not respect patients' wishes to refuse treatment when they become unable to articulate them. Patients also fear a personally degrading and financially bankrupting prolonged terminal illness.[3] Patients request PAS because they feel they have no alternative if they want to maintain control over the time and circumstance of their death.

Competent patients have the moral and legal right to refuse life-prolonging medical therapies, including hydration and nutrition, even if their death will result. It is almost always rational for a patient dying of a terminal illness to wish to die sooner rather than later, in order to avoid suffering. Physicians have the responsibility to carefully counsel patients about their prognosis with and without therapy and with different types of therapy.[4]

However, patients do not have the correlative moral or legal right to request that physicians provide them with special therapies or acts, such as PAS or VAE, particularly if physicians judge that such requests are medically inappropriate. Physicians are neither morally nor legally required to respond to patients' requests that are not medically indicated, including some requests to withhold or withdraw life-sustaining therapy. Physicians should decide whether to accede to a patient's request depending upon the physician's judgment about the medical, moral, and legal appropriateness of the request.[5]

Terminally ill patients contemplating suicide do not necessarily wish to die, only to be relieved of their suffering. Often, they choose to commit suicide or to ask their physician to help them commit suicide because they believe death is the only solution to relieve their suffering. When faced with a terminally ill patient's request for PAS, the physician should attempt to provide optimum palliative care, thereby eliminating the need for the patient to commit suicide.

Most experienced clinicians can recall a few cases of suffering so profound and intractable that a coherent argument could be made that it would be morally justified for the physician to provide assistance to the patient's suicide. However, there is an important practical distinction between the theoretical moral permissibility of PAS in these rare, arguably justified cases, and the public policy decision to legalize PAS. The decision to legalize PAS produces an unavoidable series of negative consequences whose totality produces more harm than benefit. This conclusion was reached by the Council on Ethical and Judicial Affairs of the American Medical Association, which reaffirmed its opposition to legalizing PAS in 1992.[6]

Findings and Conclusions

PAS would rarely be necessary if physicians were appropriately trained in and willing to perform better palliative care of the terminally ill, including aggressive control of pain and other sources of suffering in dying patients.[7] However, because some sources of suffering in dying patients cannot be controlled adequately, even with optimum palliative treatment (e.g., loss of bowel control, unpleasant odors, bodily disfigurement, despair, shame, and isolation), there will remain a demand for PAS. Physicians can minimize this demand by improving their technical and interpersonal skills in providing terminal care.

The only potential benefit derived from permitting PAS in VAMCs in those jurisdictions that have legalized it is that certain patients may regard the VHA as caring and sensitive to the needs of dying patients. However, there are a number of serious public policy problems created by legalizing PAS that would be avoided by not doing so.

Of greatest relevance here is the potential for damage to the public and patient confidence in the VHA and its facilities and personnel if the veteran population believes that physicians are helping or encouraging patients to commit suicide to save the system money. In these days of budgetary constraints, the agency must be particularly sensitive to any public perception that the welfare of our patients is being jeopardized to save money. Accusations of this type already have been leveled

against our policy in *VA Manual M-2*, Chapter 31 to withhold and withdraw treatment. These accusations would be more difficult to defend if PAS were permitted in VHA.

On a more general level, legalization of PAS could cause the loss of public confidence in the medical profession if physicians were perceived as killers instead of healers. The goal of medicine is to heal, counsel, and comfort. Actively assisting patients' suicides crosses the line between healing and killing and violates the moral basis for the practice of medicine.[8]

Another risk of legalizing PAS is that dying patients may feel "the duty to die." Terminally ill patients may "request" PAS because of perceived pressure from family members to save money from a lengthy terminal hospitalization. Asking for PAS because of pressure from others subverts the concept of voluntariness.

Similarly, terminally ill patients could feel subtle or overt pressure from physicians to "request" PAS. Physicians may no longer feel it necessary to work hard to provide optimal palliative care to dying patients and, rather, could advocate directly or by inference that the patients could commit suicide. Patients may agree with this suggestion because they think the physician must know what is best for them.

Legalizing PAS would require the development of a bureaucracy of legal sanctions and permissions to prevent abuse. This bureaucracy could further compromise the relationship between the physician and the dying patient. Despite bureaucratic legislation intended to prevent abuse, it is likely that that abuses will occur.

How should VHA physicians respond to a terminally ill patient's request for PAS? First, the physician should investigate the reasons for the request. The physician should attempt to treat all sources of the patient's suffering to the fullest extent possible. If after the application of maximal palliative therapy, the patient continues to request PAS, the physician should notify him or her of the full right to refuse all life-prolonging therapies, including hydration and nutrition. Such patients can be educated that they may voluntarily refuse to receive life-

sustaining hydration and nutrition.[9] Patients who have refused hydration and nutrition should be educated that their decision is revocable should they change their mind. Reversible disorders, including depression, should be treated to the fullest extent reasonable.

Most terminally ill patients dying of lack of hydration and nutrition do not suffer if managed properly. Indeed, the forced hydration and nutrition of terminally ill patients can cause suffering from nausea and pulmonary edema. Physicians caring for patients who wish to die from refusal of hydration and nutrition have the duty to help maintain their comfort during the one to two week dying process. Physicians should be willing to order proper mouth care and use opiates and benzodiazepines to appropriately minimize any suffering during dying. This method of dying from dehydration has been used successfully in hospice patients.[10-12]

Refusal of hydration and nutrition has several public policy advantages over legalizing PAS. It is already legal and requires no change in the physician's role as healer, counselor, and caregiver. It maintains the proper emphasis on the physician's role of providing adequate terminal care to his dying patients. The one to two week dying period allows the patient time to discuss the decision with family members and to reconsider. Finally, refusal of hydration and nutrition is less likely to be abused than PAS. It is unlikely that a patient would feel pressure from family members or physicians to die of refusal of hydration and nutrition.

Recommendations

1. PAS should not be legalized in the VHA. If a state legalizes PAS in the future, the VAMC physicians should explain that PAS is not permitted within VHA hospitals and clinics. Neither should VHA pay for a patient's PAS in another hospital.
2. Physicians need to learn and practice optimal palliative care for their dying patients, thereby both to restore patients' faith that the medical profession can and is willing to prevent unnecessary suffering during dying, and to reduce the need for requests for PAS.

3. If maximal palliative care is insufficient to stop a terminally ill patient's request for PAS, the patient can be educated that he may refuse hydration and nutrition.
4. VHA should add a chapter to the *VA Manual* outlining a comprehensive policy on the management of the dying patient to include DNR orders, advance directives, hospice care, pain management, and other aspects of terminal palliative care.
5. A national educational effort should be mounted to instruct VHA physicians, other staff members, and the families of patients on the principles of excellence in the management of the terminally ill dying patient.

Notes

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8. Ethical Considerations in Research: Participants with Impaired Consent Capacity

Some Governing Principles

1. The opportunity to participate in research should extend to all classes of individuals. Vulnerable populations of participants may need additional safeguards to protect their autonomy and health.
2. Participation in research must be contingent on the voluntary informed consent of the potential participant or an appropriate surrogate. Consent from the participant or surrogate, no matter how well-informed or how well it is thought to reflect the participant's interests, does not relieve the investigator and the reviewing entities from the obligation to conduct ethical research. A surrogate is someone who is empowered to authorize the participation of someone else as a subject in a research protocol. Typical surrogates include parents, adult relatives, and guardians. Occasionally, the holder of a Durable Power of Attorney for Health Care is asked to serve as a surrogate. A surrogate may exercise the noted authority only if the subject is incapable of consenting, the research poses not more than "minimal risk" to the subject, and the research is judged to be in the subject's best interests. Surrogates must avoid conflicts of interest in deciding to submit their charges to research.
3. Research protocols must be designed to take into account the special needs of individuals with ICC when developing procedures to minimize risks.
4. Research participants must not be deprived of available standard

treatments for the purposes of a research trial (e.g., given placebo arms) without adequate scientific and ethical justification. Withholding of standard, therapeutic treatments from control groups always bears a strong and distinctive burden of proof.

5. Policies that regulate human experimentation must strike an honorable balance between community and individual interests.

Discussion

Purpose

In this report, we discuss some general governing principles for research involving human participants. We are aware that additional important ethical principles may also be relevant to research. Principles governing human experimentation are the same for individuals with ICC[1] as for any research participant. However, differences may arise in implementation of those principles. These differences largely consist of additional safeguards to assure that the autonomy and health of vulnerable participants are protected. At the outset, we emphasize the heavy burden of responsibility placed on clinical investigators, research institutions, reviewing entities, and sponsors of research to protect the well-being of all participants and to merit the trust placed in them by the participants and their surrogate decision-makers.

Governing Principle 1. The opportunity to participate in research should extend to all classes of individuals. Vulnerable populations of participants may need additional safeguards to protect their autonomy and health.

VHA Mission

Mission Goal III of the *Prescription for Change*[2] is to provide excellence in education and research. The concept of excellence in VHA research encompasses active support of high quality research to stimulate and promote scientific advances that will improve clinical care and increase biomedical knowledge. VHA research is conducted within an environment that respects all participants as important partners in the process.[3] Our institutional values and principles

establish the framework for our research practices.

In VHA, the potential population of research participants includes many individuals who are among the sickest, most economically disadvantaged citizens in our nation. These veterans have made a contribution to our country through military service and many are eager to contribute again through participation in research. We must assure that opportunities to participate in research are accompanied by carefully constructed, thoughtful safeguards that make every effort to protect the health and welfare of the participants.

International Guidelines for Vulnerable Participants

"The voluntary consent of the human participant is absolutely essential."[4] Thus begins the Nuremberg Code, which remains the most rigorous standard for protection of human participants in research. The Nuremberg Code was written from the human rights perspective of war crime trial judges who were interested in protecting future research participants from abuse or harm. The rapid expansion of clinical research after World War II produced important new treatments that affected the health of communities and had significant financial impact. As the value of biomedical research to individuals and communities increased, limitations on participation and the protection of individual rights and autonomy promulgated in the Code were re-examined.

Some populations of individuals were identified who shared characteristics that made their decision to participate in research more easily influenced by factors extraneous to specific research-related issues. Other groups lacked the decision-making capacity to provide consent for themselves or to withdraw from a research protocol once they enrolled. All these groups of individuals may be included in the general category of "vulnerable."[5] If the Nuremberg Code was strictly followed, they would be excluded from participation in research because they cannot provide informed, voluntary consent for themselves.

However, these vulnerable populations of potential participants

may have a strong interest in the improvement of treatment and further understanding of the serious and often profoundly disabling disorders from which they suffer. By excluding these groups from research participation, they may be deprived of potentially beneficial treatments that are available only in the context of a research protocol. Likewise, the opportunity for research into the pathophysiology and appropriate treatments for their disorders will be irretrievably lost if these participants are never permitted to participate in research. When we consider research protocols that involve participation of vulnerable participants, we have moved beyond the human rights-based standard of Nuremberg.

In involving these participants, ethical concerns arise in appropriately balancing respect for persons and potential benefits and risks to individual research participants. Participation by these groups of individuals may also provide benefits to larger communities of patients and others in the forms of improved treatment, increased medical knowledge, and better utilization of health care resources. How to balance the rights and welfare of individuals with other societal needs raises additional difficult ethical issues.

Subsequent professional international guidelines from the World Medical Association (Declaration of Helsinki) and from the Council for International Organizations of Medical Sciences specifically permitted research in populations from whom consent could not be directly obtained or who were vulnerable.[6] Both organizations also provided recommendations for safeguards for these populations when participating in research. Although these international guidelines have no legal authority in the United States, they provide a some international perspective in discussing these issues.

U.S. Guidelines for Vulnerable Participants

In 1974, the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was established to consider ethical issues in human experimentation. In 1979, the Commission issued the *Belmont Report: Ethical Principles and Guidelines*

for the Protection of Human Subjects of Research.[7] The report summarized the Commission's deliberations on the basic ethical principles underlying research involving human subjects and outlined guidelines for conducting research in accordance with those principles. The Commission also issued other reports, some of which specifically addressed concerns of involving vulnerable participants in research.[8] The reports of this Commission played an important role in providing a basis for the development of current federal regulations known as the "Common Rule."[9] These federal regulations permit research participation by certain vulnerable populations with additional safeguards, including consent from surrogates.

The Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH) has published guidelines for human experimentation. These guidelines devote an entire chapter to consideration of "special classes of participants" or vulnerable populations.[10] OPRR considers vulnerable populations to be groups of individuals who, due to defects in capacity or autonomy, may not be able to give informed or voluntary consent that is consistent with their own best interests. Vulnerable populations listed in the "Common Rule" include children, prisoners, pregnant women, mentally disabled persons, and educationally or socially disadvantaged groups. Additional special classes that OPRR considers potentially vulnerable and includes in their guidelines are: traumatized and comatose patients, terminally ill patients, elderly/aged persons, minorities, students, employees, and normal volunteers.

Equitable Selection of Participants

General safeguards for participants with ICC include criteria for selection of participants that recognize concerns for justice and fairness. As a general principle, individuals with ICC shall only participate in research dealing with a condition or circumstance unique to the participant population and for which unaffected persons could not provide the information sought. If non-impaired participants would be adequate for the conduct of the research protocol, then there is no need to involve a vulnerable participant population. These

individuals cannot be considered for participation in research simply because they are conveniently located (e.g., institutionalized patients). In rare instances, however, inclusion in a research protocol may provide the only possibility of survival from a fatal disease that is unrelated to the cause of the individual's incapacity and is expected to produce death in a short period of time. The potential benefit of participating in such a protocol may justify inclusion of a participant with ICC. In such instances, and with individual approval by a reviewing body, surrogates may choose on a best interest basis to consent on behalf of the participant with ICC.

VA Patients as a Special Vulnerable Population

VA patients considered as a group may share some general characteristics with other vulnerable populations.[11] Veterans frequently come to VA because they are economically disadvantaged and are unable to afford private health care. If they are dissatisfied with their VA care, they may have no other health care option and may perceive themselves as "captive" in the VA health care system. In spite of assurances to the contrary, they or their surrogates may fear abandonment or inferior treatment if they reject an opportunity to participate in research. They may also feel a personal obligation to VA because "free" care is being provided to them and may not appreciate that they paid for their care "up front" during their military service. Other veterans, out of concern for the survival of VA in fiscally constrained times, view research protocols as a way of enhancing the reputation of VA and protecting future agency funding. Any of these issues may influence the "voluntariness" of the decision-making process.

The conduct of research in vulnerable populations requires careful consideration of ethical issues in protocol design, the consent process, and monitoring of participation.[12] This imposes special responsibilities to safeguard the participants on the investigators, institutional review boards, surrogates, sponsors, and other individuals who participate in, fund, or provide oversight for the conduct of this research. The safeguards that may be employed for vulnerable participants are discussed below in the context of the appropriate governing principle.

Governing Principle 2. Participation in research must be contingent on the voluntary informed consent of the potential participant or an appropriate surrogate. Consent from the participant or surrogate, no matter how well-informed or how well it is thought to reflect the participant's interests, does not relieve the investigator and the reviewing entities from the obligation to conduct ethical research.

General Consent Considerations

Obtaining informed consent in medical practice is a means to promote self-determination of patients by involving them in the decision-making process. This demonstrates a respect for autonomy of the individual and his/her right to exercise choice in health care. The provider may make recommendations, but he/she is bound to respect the patient's choice. This may be difficult when the provider believes the patient has made a poor choice that does not promote the patient's best interests. However, promoting and protecting a patient's well-being through beneficent action includes respecting the patient's autonomy.

An important difference between health care and research decision-making is in the nature of the choice being offered. By its very nature, research is experimental. If the benefits were known with any degree of certainty, it would not be necessary to do the experiment. The experimental nature of the undertaking makes it more difficult to weigh risks and benefits or to assess when risks are too high. Because the likelihood of benefit may be unknown or incompletely known, it also is more difficult to compare the potential value of participation in a research protocol against a standard treatment.

Full Information

The experimental nature of research participation increases the importance of providing full information to participants and the absolute requirement for the consent to be voluntary. It is standard practice to provide full detailed information in written form covering all aspects of the proposed research, including the purpose of the research, who will be involved as participants, procedures or methods,

known benefits, all possible risks, alternative options, financial considerations, and rights of the research participant. This often goes well beyond the level of detail in what would be considered a "complete" consent discussion in the clinical setting for the purposes of treatment. The practice of full disclosure is an attempt to assure that the potential participant has every possible piece of information that might be important to one in making a decision.

In obtaining consent for research participation, as in the clinical setting, stakeholders other than the patient/participant have important interests of their own. Conflicts of interest between the participant and other stakeholders can compromise the consent process. Investigators need to enroll participants in order to conduct research and may benefit either professionally or financially from the research. Research institutions benefit financially from funded research and enhance their reputation. Sponsors of the research, whether funding agencies pursuing larger societal health goals or commercial concerns trying to market a product, also have their own interests. One response to minimize the influence of these potential conflicts of interest in the consent process is to establish regulatory and oversight mechanisms. These protections afford some assurance of fully informed and voluntary consent, but they cannot guarantee it. The responsibility for respecting the autonomy of the individual ultimately lies with each investigator. We believe that a thoughtful, committed investigator who is aware of potential biases and who respects participants may be the most important means of assuring informed and voluntary consent for research.

"The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity." [13]

Voluntary Consent

Many research participants have difficulty in distinguishing between what constitutes standard treatment and what is experimental. The important subtleties of these distinctions may be

even more confusing for participants with ICC. Individuals often believe that their physician or other providers are acting in their best interest and when presented with an opportunity to participate in research often mistake this as the treatment recommendation of the provider. This may confuse their understanding of the likelihood of benefit to themselves by participation. This "therapeutic misconception" is based on their trust in the provider to do what is best for them.[14] Patients or potential participants will persist in this belief even when randomization procedures and differences in protocol arms are carefully explained. Investigators may also unwittingly confound state-of-the-art treatment with experimental treatment, particularly when standard treatments are not terribly effective. The investigator may view the research protocol as the only good "treatment option" for the patient/participant and may believe that acting beneficently means encouraging participation in the research protocol. Maintaining objectivity about the experimental nature of the protocol can be difficult for all parties involved. If objectivity is a concern, it can be partly ameliorated by having consent obtained by someone other than the participant's health care provider, if he or she is also the investigator, whenever possible.

Additional measures can be used to enhance an individual's ability to provide consent. Providing a non-stressful environment, using simple language, being receptive to questions, and responding thoughtfully in a non-hurried fashion may have significant impact on the level of a participant's understanding. A consent facilitator, either a surrogate, friend, or health care professional may provide support for the potential participant, either of a psychological nature and/or by answering questions or helping with explanations during the consent process. In some cases, a neutral consent auditor who is not acquainted with the participant and has no stake in the protocol may provide an objective third-party perspective on the individual consent process by observing the discussion and assessing whether the participant was capable of consenting, gave assent, or refused consent.[15]

Consent from Individuals with ICC

Consent for research participation must be obtained with meticulous attention to ethical considerations. Participants with ICC present special challenges.[16] These individuals have deficiencies in their abilities to reason (capacity) that will compromise their understanding of information presented. Their autonomy may be threatened by their perceptions of unequal power relationships, which, especially in institutionalized participants, may compromise the voluntary nature of their decisions. While an important concern is protecting those who are unable to give consent for themselves, investigators should be careful not to unnecessarily abridge the rights of those who can consent. A particular diagnostic category does not necessarily indicate complete compromise of decision-making capacity. Potential participants should be involved as fully as possible in the decision-making process.

To have decision-making capacity, one must be able to understand the information presented, to appreciate the consequences of acting on that information, be able to make a choice about a particular treatment or protocol, and communicate that choice. Decision-making capacity has often been described as a threshold ability (you either have it or you don't). In fact, a more useful clinical model is that of a sliding scale along a continuum of more or less risky and complicated procedures. This model is useful in ascertaining the ability of a given individual with ICC to consent to a specific research protocol. Using a sliding scale threshold, one's qualifications to give consent depend to some extent on the inherent risk of the procedure proposed and on the likelihood of direct benefit, as well as the usual criteria for decision-making capacity.[17] For example, for procedures that involve risks that may have serious, disabling, or fatal consequences, the threshold moves to a higher quality of decision-making capacity. Assessing capacity in the context of a specific research protocol may allow more participants to be involved in the decision-making process.

Determination of an individual's consent capacity is usually left up to the investigator obtaining consent. If the investigator is uncertain about the individual's ability to provide voluntary and informed consent, he/she may seek the assistance of another health professional

such as a psychiatrist, psychologist, or behavioral neurologist to assess the individual's capacity in a more detailed and complete fashion. For the purposes of informed consent for health care in VHA, when a patient is determined to lack decision-making capacity based solely on a psychiatric diagnosis (e.g., schizophrenia), then a psychiatrist must be consulted.[18] The psychiatrist must agree that the psychiatric illness has impaired the individual's capacity so severely that he/she is not capable of health care decision-making. This consultation safeguard protects individuals with a psychiatric diagnosis from being denied the opportunity to participate in decision-making when capable. Use of this type of consultative safeguard in the research setting might promote autonomous decision-making for individuals with a psychiatric diagnosis.[19]

Consent from Institutionalized Individuals

The voluntary nature of consent may be more easily compromised for institutionalized individuals. They may see consent to research as an opportunity to appear "rational" and increase their chances of an earlier discharge. They may feel emotionally dependent on caretakers and want to "please them" or be afraid of angering them and subsequently losing privileges. The opportunity afforded by a research protocol to receive extra attention or be moved to a more pleasant unit or facility may be a significant inducement to participation. Consent auditors may help provide an objective appraisal of a consent discussion. Likewise, in this group it may be especially important to have someone obtain consent who is not involved in the day-to-day care of the patient/participant or who is not in a position of authority over the participant. Another moderating influence may be the establishment of a local facility committee of institutionalized patients who review protocols to be used in the facility and who can provide patient input at the outset regarding concerns about risks or inducements.[20]

Advance Consent for Research

In some cases, it may be possible to promote participant self-determination by eliciting their wishes regarding future research participation at a time when they are capable of consenting. The NIH Clinical Center routinely utilizes a Durable Power of Attorney for Research (DPAR), which designates an authorized surrogate to give consent for participation in research. This has several advantages. It provides an opportunity for potential participants and future surrogates to explore the possible options and discuss levels of risk and benefit the potential participants might be willing to undertake. It may also allow the potential participants to discuss whether they would be willing to participate in future protocols for altruistic reasons, assuming some personal risk without any certainty or realistic possibility of direct benefit to themselves, in the hope that the knowledge obtained would benefit others. When surrogates are identified in advance, an important educational opportunity arises to explain substituted judgment and best interests decision-making and when each is appropriate, their rights as surrogates, and their responsibilities to the participants.

Another possible option is an advance directive for research or a Ulysses Contract, which is completed while the participant has capacity to consent.[21] This documents the potential participant's willingness to participate in research at a future time when he/she is no longer able to give consent. This document can be used alone or in combination with a DPAR as an indication of the participant's wishes. The Ulysses Contract must be assessed prior to participation in any specific protocol to ensure that participation is consistent with the details and qualifications of the prior consent. The Ulysses Contact should not override a participant's refusal to continue participation once research is begun.

Surrogate Consent for Research

For those individuals whose decision-making capacity is so impaired that they cannot provide consent, a surrogate decision-maker must be identified who will be responsible for making decisions on the

individual's behalf. The surrogate acts in the participant's place to make decisions and should be given any information the participant would be given, allowed to ask questions and generally treated in the same manner as the participant would have been if he or she had capacity. The best surrogates are those who know the participants well and have discussed their values and desires prior to the participants' loss of capacity. Current VHA research policy limits the list of potential surrogates and does not include other more distantly related individuals and friends who may be valuable as surrogates, particularly if they had regular and close contact with the participants.[22] If the goal in selecting surrogates is to identify the individual who is most able to represent the participants' interests, then VHA may need to reconsider who should be permitted to provide surrogate consent to research.

In addition to identifying the legally authorized surrogate, one should also consider whether that surrogate is also an ethically valid surrogate. This individual should know the participant and the participant's preferences for research participation, be willing and available to serve as surrogate, be capable of providing informed consent, and understand his or her responsibilities with regard to decision-making for the participant. When the participant's preferences are known, the surrogate is obligated to make decisions consistent with those preferences (substituted judgment). If the participant's preferences are not known, then the surrogate should attempt to utilize any clear evidence of preferences that may be available, e.g., written statements, personal conversations, knowledge of the participant's values based on a long and close relationship. If there is no available evidence to guide the surrogate, then decisions must be based on the best interests of the participant as interpreted by the surrogate. In the last circumstance, input from other friends, family members, or the personal physician of the participant may be helpful.

Fluctuating Capacity to Consent

Some research participants may have sufficient capacity to consent at the outset, but may be reasonably expected to lose capacity during the course of the research due to their underlying disorder. In this case, the investigator has an obligation at the time of enrollment to identify,

in collaboration with the participant, a surrogate who will be able to make decisions in the event that the participant loses capacity. The investigator must turn to the surrogate if the participant loses capacity during the research. The participant may further safeguard his/her interests by taking the opportunity to discuss with the surrogate his/her wishes regarding participation in the current protocol or future protocols.

Preserving the Right to Withdraw

While procedures for consent are especially labor intensive at the beginning of participation, a signature on the consent form does not end the process. In fact, the process is ongoing until participation ends. Every participant has the right to withdraw at any time from a protocol if he/she chooses to do so. Participants who lack capacity or who have fluctuating capacity may not be aware that they have the right to withdraw and a surrogate must be available to speak for them. When consent for participation has been refused or withdrawn, mechanisms must be in place to ensure that such refusal will in no way compromise or limit the access of the participants to the same quality of health care provided to those who do participate. Protection of the participants' right to self-determination ultimately falls on the investigator, who must be certain on a continuous basis that the surrogate is informed if and when the subject with varying decisional capacity loses that capacity.

Assent

Assent is "the willingness and, to the extent possible, the knowledgeable participation of those unable to give consent."[23] The investigator has an obligation to obtain the participant's assent to participation, when possible, if a surrogate provides legal consent for participation in research. Assent, like consent, is an ongoing process that includes the right to withdraw at any time. Severely impaired participants who no longer have a level of understanding sophisticated enough to provide consent for themselves are still autonomous individuals whose right to exercise self-governance, insofar as they are capable, should be respected. Assent is a safeguard to preserve the voluntary nature of participation.

Current VHA policy requires assent of the participant with ICC. "Under no circumstances may participants be forced or coerced to participate."[24] Participants who resist or who are seriously distressed by some aspect of their participation should not be forced to participate even if all other requirements for the research have been satisfied. In some situations, investigators may choose to have a consent auditor present during the discussion to confirm that the participant has indeed assented. For studies that include potential for harm or serious dislocation or discomfort, the willingness of the participants to continue should be monitored in an ongoing fashion, as an additional safeguard, by qualified professionals who are not themselves involved in the research.

In decisions regarding research participation, surrogates have not been given the authority to override an impaired participant's refusal to assent. It may be troubling, for a surrogate and others who are concerned about the participant's welfare, when a participant with ICC refuses to participate in a study that holds a possibility of providing significant benefit. Surrogates may believe that in order to fulfill their responsibilities to the participant they should be allowed to determine the relative importance to the participant of self-governance versus the likely health benefits of participation. Currently, this thorny issue has been legally resolved in favor of participant self-determination by requiring assent and not permitting surrogates to override refusals. This approach places a higher value on the autonomy and dignity of the impaired individual than health benefit and provides a limited safeguard against forcible participation of individuals with impaired capacity.

Research Participation without Consent

On October 2, 1996, the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) published amended regulations on informed consent (in the *Federal Register*). These regulations provide for an exception to the requirement that researchers obtain and document informed consent from each human participant, or his or her legally authorized representative, prior to

initiation of an experimental intervention. The exception would apply to human participants who are in need of emergency medical intervention, but who cannot give informed consent because of their life-threatening medical condition and who do not have a legally authorized person to represent them. These regulations also include requirements for consultation with representatives of the community from which the participants will be drawn, requirements for public disclosure, and the establishment of an independent data monitoring committee to exercise oversight of the research.

This action is significant because, for the first time, federal regulations permit research without the informed consent of the participant or legal representative. This action was taken after a coalition of regulators, researchers, bioethicists, and others expressed opinions in print and in a public forum sponsored by NIH and FDA. The forum considered the necessity of allowing emergency research to go forward despite the practical impossibility of requesting informed consent from participants who suddenly, because of emergency medical situations, had either significantly impaired or absent decision-making capacity. Publication of the new regulations is also significant because it signals for the first time that federal regulators recognize that rigid adherence to rules that require informed consent from participants who cannot give it (because of an emergency medical condition) may deprive participants from the chance for benefit from potentially life-saving interventions. Thus, the regulations provide that, with certain safeguards, the potential of benefit to participants may override the requirement to obtain informed consent for research.

It should be noted, however, that though there is a requirement for a community representative to provide input into the process, this is not a balancing of community interest versus individual interest. Instead, the representative is to represent the community of potential participants, i.e., individuals who might later become patients who could benefit from the proposed intervention. Thus, this regulation attempts to balance the autonomy interests of the individual with the interest of the individual to receive potentially beneficial therapy when he/she cannot consent. The fact that for the first time, with certain

safeguards, the potential of benefit to the participant may outweigh the autonomy interests of the participant may have significant implications for clinical investigations in individuals with other conditions which impair decision making capacity.

Governing Principle 3. Research protocols must be designed to take into account the special needs of individuals with ICC when developing procedures to minimize risks.

Some General Considerations

As with all research involving human participants, protocols must address a scientific or clinical question of importance and must be designed so that high quality, reproducible data may be obtained. Preliminary work in animals or model systems should be done when possible, and human participants must be essential to the project.[25] All research involving human participants should strive to minimize the risk to participants. In participant populations with ICC, there are additional criteria that should be considered. These include: 1) careful weighing of the most favorable risk/benefit ratio; 2) monitoring participants, not only for adverse effects, but also for ongoing consent capacity; 3) stopping rules that will identify participants having difficulty so they can be withdrawn by the investigator as soon as possible; 4) providing access to follow-up medical care for participants who have adverse effects and are removed from the protocol.

Evaluating Benefit and Risk

Risk may be evaluated in its relationship to potential benefits.

"Most favorable" risk/benefit ratio requires that: 1) the risk is justified by the potential direct medical benefit to the participants (i.e., the potential direct medical benefits to the individual participants outweigh the risks to those participants), and 2) the relation of the potential benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches."[26]

This rendering of the concept of risk takes into account not only the proposed procedure, but also the availability of other treatments (standard or otherwise) and considers exclusion from them as an additional possible risk. This protects the status quo of participants so that theoretically the research should not make them worse off than when they began participation. Current VHA policy is consistent with this approach.[27]

Levels of risk in human experimentation in the United States are categorized as minimal, minor increase over minimal, and greater than a minor increment over minimal risk.[28] Individuals with ICC are candidates for protocols that hold out a possibility of direct benefit, but pose only minimal risk. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research recommended that a minor increase over minimal risk also be permitted if direct benefit is expected.[29] The NIH Clinical Center and the American College of Physicians take a similar position.[30] Risks may be of a psychological, as well as physical, nature. For some participants, simply a serious disruption in daily routine may be quite stressful and may represent a significant risk to their well-being.[31]

There is much less consensus on whether individuals with ICC should ever be candidates for research that is not directly beneficial to the individual participant. The National Commission takes the position that if no direct benefit is expected, then the information sought must be of vital importance in treating the disorder and a National Review Board must be consulted. (No such board exists.) The American College of Physicians position paper takes a conservative approach that does not permit surrogates to consent for research that is greater than minimal risk and is non-therapeutic/non-beneficial to the participant. The NIH Clinical Center permits research of this type but with increased oversight and safeguards.[32] The lack of consensus among professional groups reflects the ongoing controversy in our society about how much risk an individual may undertake for the benefit of others. These concerns are summed up by Hans Jonas:

"Let us…remember that a slower process in the conquest of disease

would not threaten society, grievous as it is to those who have to deplore that their particular disease be not yet conquered, but that society would indeed be threatened by the erosion of those moral values whose loss, probably caused by too ruthless a pursuit of scientific progress, would make its most dazzling triumphs not worth having."[33]

Minimizing Risks: Inclusion and Exclusion Criteria

Investigators are charged with minimizing risks to all research participants and additional safeguards may be needed to protect the welfare of vulnerable participants. Inclusion and exclusion criteria for enrolling participants help screen out those individuals who might be expected to have a higher risk of adverse events while enrolled in the study. These criteria may include both psychological and medical screening criteria.

Minimizing Risks: Monitoring Participation and Stopping Rules

Participants may be withdrawn from participation in a research protocol at their own or their surrogate's request or at the request of the investigator. Participants with ICC, because of their deficiencies in decision-making abilities and, in some cases, vulnerability to outside influences, may not appropriately exercise their right to withdraw. Surrogates for those who lack capacity are not always available on a daily basis, may be unaware of problems, and may have uncertainty regarding their rights and responsibilities. Careful monitoring of participants during participation in research protocols ensures that safeguards in place to protect their interests (autonomy and health) are working effectively. Monitoring is especially important to safeguard participants who may have provided consent initially, but who lose decision-making capacity during the study. Carefully crafted stopping rules developed by the investigator identify the limits of acceptable levels of adverse effects.[34] They assist in identifying individuals whose levels of risk have become unacceptable so they may be expeditiously removed from the study protocol.

Provision of Needed Medical Care to Study Dropouts

Individuals with ICC may have special difficulties in seeking and obtaining medical treatment at the appropriate time. Participants with ICC may have limited abilities to recognize the need for additional care or may have difficulty seeking care independently and may not seek it appropriately. If participants with ICC are removed from a protocol at their own request, or at the request of the investigator, because they are having difficulties beyond an acceptable level, the investigator has the responsibility to see that the participants are referred back to the appropriate health care provider. Investigators should assist participants who withdraw or are withdrawn in arranging for adequate follow-up care to assure that their continuum of care is maintained. With the permission of the participant or surrogate, any information the provider needs regarding protocol participation should be made available to them.

Governing Principle 4. Research participants must not be deprived of standard treatments for the purposes of a research trial (e.g., given placebo arms) without adequate scientific and ethical justification.

Minimizing Risk

For participants with ICC, the issues regarding risk in protocols with placebo arms are no different from those of any other class of participants. Investigators and IRBs should pay careful attention to safeguarding the welfare of all participants when they may be randomized to a placebo arm. Withholding standard treatment, no matter how ineffective or fraught with side effects that treatment is, may still pose an additional risk to participants. A number of ways to minimize risks are set out in Governing Principle 3. As in other types of protocols, participants with ICC may need additional or strengthened safeguards.

Creating a Useful Dialogue

All research participants, especially those with ICC, should be protected from unacceptable or unnecessary harms. Withholding an

available treatment from participants randomized to a placebo control arm is not always an unacceptable or unnecessary harm. The issue of the use of placebo arms rather than active controls in randomized controlled trials (RCT) has been the subject of heated discussion in the bioethics and medical literature. Those who argue that placebo arms are almost always unethical and others who do not believe that investigators should be required to justify placebo arms scientifically and ethically have taken such extreme positions that reasonable discussion and achievement of some sort of consensus becomes very difficult. These extreme positions may fail to recognize both the scientific and ethical complexities involved in the design of research trials and protection of human research participants. A more reasoned approach balancing the requirement of good science and the ethical obligations to human research participants may be necessary if we are to negotiate the complexities of this important issue successfully.[35]

It is well-established that the RCT is the best way to evaluate the efficacy (including both sensitivity and specificity) of a new therapy. The need for including placebo arms, especially in determining efficacy of treatments for disorders with a variable course and fluctuating symptomatology, has been discussed in detail elsewhere.[36] Some opponents of placebo arms assert that the motivation for their use is simply to facilitate quicker, smaller studies in order to market therapies that could be less useful than standard treatment. This generalization inaccurately represents the many possible legitimate and justifiable reasons for using placebo arms. On the other hand, there are situations in which a careful scientific re-evaluation of a proposed protocol may reveal that a placebo arm is not necessary to generate good data and thus allow research participants to continue on therapies that may be beneficial while on study.

Scientific Justification of Placebo Controls

Investigators have demonstrated that they can make thoughtful, scientifically based arguments for using placebo controls. This being the case, investigators should share that scientific justification with review boards, potential research participants, or journal editors in the same

way they would describe any other aspect of a study in a "methods" section in a publication. This is information that would be relevant to a potential participant who wants to make an informed decision. If the participant needs to consider whether to accept risks associated with discontinuing a current treatment or having a standard treatment withheld, then an explanation in layman's terms of why the investigator chose this methodology would be pertinent. The interest of a review board in approving a methodologically sound research protocol or a journal editor in publishing a report based on a well-designed protocol are also legitimate reasons for requiring a scientific justification of placebo controls.

Methodologically sound science is a necessary, but not sufficient, basis for determining whether a specific protocol meets the ethical standards for approval for human experimentation. Investigators are responsible for minimizing risks to participants. If a protocol with a placebo arm exposes participants to unnecessary or unacceptable risks, which could be avoided by a modification in the protocol design that would not render the results invalid, then the investigator is ethically obligated to make that modification. If standard therapy for a disorder is less than fully adequate (e.g., provides only symptom relief and is not curative, has limited efficacy in the patient population, is not universally better than placebo), a placebo arm is more easily justified and may be essential to demonstrate efficacy of a new therapy. A placebo arm may also be justified if current standard therapy is associated with serious side effects that are not associated with the therapy under investigation. It is almost always true that it is possible to balance the interests of science and the interests of research participants in such a way that valid research results can be obtained. More often than not, good science is good ethics.

Access to Better Therapies

One purpose of conducting clinical research is to identify new and better therapies. If an individual clearly benefits from an experimental treatment, the investigator and/or institution where the research was conducted may have an obligation to continue to provide that

treatment to the participant when they complete the study or when the study ends. Participants who were in placebo arms should also be offered the option of treatment if it may be beneficial. While it seems from an ethical point of view that a beneficial experimental treatment ought to be provided to a participant once the study ends, a number of procedural issues may make meeting this obligation very difficult. For example, if a research medication is off-formulary and very expensive, it may be difficult to shift sufficient institutional resources quickly to provide the drug to every participant who could benefit. This medication may also have to be provided in an open-label study if it has not been approved for the indication under study. As much as possible, investigators should try to work out a process in advance to assure that study participants who benefit from an experimental treatment will be able to continue on that treatment if they so desire. If it will not be possible to continue treatments that have proven beneficial while on protocol, then participants need to be given this information as part of the initial consent process.

Governing Principle 5. Policies that regulate human experimentation must strike an honorable balance between community and individual interests.

The preceding four principles derive from the philosophical tenets that autonomy of individual human beings should be respected and that the interest of vulnerable research participants should be protected. Nothing in Principle Five should be construed as minimizing the importance of these beliefs.

We acknowledge, however, that there are community interests, i.e., that the concerns and hopes of individuals in society, at present and in the future, should also be pursued. However, any consideration of research involving human participants, especially those with ICC, that focuses on future societal concerns must ensure that safeguards for individual autonomy enunciated in the four preceding principles are determinative.

For the past half century, the voluntary nature of the consent process for participation in research has been the keystone supporting

the structure of our regulatory process. As Burt has said in a recent paper about the legacy of Nuremberg: "They did not put their trust in the existence of 'civilized standards' among future professionals –neither in doctors who might consider whether to perform experiments nor in government officials who might prospectively or retrospectively judge the propriety of those experiments. The Nuremberg judges established, as their first line of defense against recurrence of these barbarities, the individual subject-patient armed with the principle of self determination. The implicit lesson that the Nuremberg judges drew from the trial testimony was that they could not place principal reliance on the self-restraining decency of traditional embodiments of social authority. This was the lesson taught not only by the doctors' trial but by the preceding war crimes trials of high government officials."[37] Our inability to account for the conduct of the Nazi experiments by well-known, respected professionals in medicine and science haunts us as we attempt to safeguard against their recurrence. In our concern for protecting individuals from the possibility of some future research enterprise run amok, we may have stifled open dialogue about the proper relationship between individuals and the community in which they live, their obligations to that community, and the relevance of community interests in research.

As other codes of research conduct have been promulgated since the Nazi Holocaust, the absolute prohibition on participation by individuals who cannot give consent has been re-examined. We routinely use surrogates to provide consent for children and those with severely impaired consent capacity. We routinely allow individuals from vulnerable groups who may not be truly capable of consenting freely to participate in research while requiring some additional (unspecified) safeguards for their welfare. Terminally ill patients regularly participate in research that offers them no direct benefit for altruistic reasons, hoping that future patients may benefit. There is recognition that some vulnerable groups of participants may or may not benefit individually from research, but that the community as a whole benefits from their participation. VHA research policy takes the conservative and widely accepted position that "incompetent people

will not be subjects of research which imposes a risk of injury unless that research is intended to benefit the subject and the probability of benefit is greater than harm."[38]

The issues of who benefits from research, balancing community and individual interests, obligations of the community to safeguard all individuals and especially vulnerable individuals, and the obligation of individuals participating in research to the larger community need to be opened for legitimate discussion. We need to assure that our research practices reflect principles that have had open, thoughtful consideration and input from all stakeholders. This requires us to step out of the shadow of Nuremberg and grapple with the complex relationships and competing priorities of individuals and their communities. If we are to protect human participants in future research, we need to explore our human values as communities as well as individuals, establish our principles for the conduct of research, and attempt to achieve some consensus on an honorable balance of our moral obligations to each other and to society.

Notes

1 Impaired consent capacity (ICC) may be defined as "the inability to provide informed consent to participate in a specific protocol. ICC is not a global assessment of a subject's cognitive status; a subject may be able to consent to one protocol, but not another." Personal communication, David Wendler, February 1996.

2 Kizer KW. *Prescription for Change*. Department of Veterans Affairs. Washington, DC, 1996.

3 This paper reviews principles that generally have relevance for all types of research involving human participants, e.g., medical, behavioral, rehabilitative, etc.

4 Nuremberg Code. *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10*, Vol. 2, pp. 181-182. Washington, DC: US Government Printing Office, 1949.

5 Robert Levine described vulnerable in this way "…those who are

relatively (or absolutely) incapable of protecting their own interests. More formally, they have insufficient power, prowess, intelligence, resources, strength or other needed attributes to protect their own interests through negotiations for informed consent," in: *Ethics and Regulation of Clinical Research*. Second Edition. New Haven: Yale University Press, 1986, p.72.

6 World Medical Association. *Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects*. Adopted by the 18th World Medical Assembly, Helsinki, Finland, 1964, and as revised by the 41st World Medical Assembly, Hong Kong, September 1989. The current CIOMS guidelines for research were reprinted without the long commentaries in "International Research Guidelines." *Bulletin of Medical Ethics* November 1993;9-11.

7 US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. Washington, DC: US Government Printing Office, 1979.

8 US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *Report and Recommendations: Research Involving Those Institutionalized as Mentally Infirm*. Washington, DC: US Government Printing Office, 1978 and *Report and Recommendations: Research Involving Children*. Washington, DC: US Government Printing Office, 1977.

9 In June 1991, the final federal policy for protection of human subjects known as the "Common Rule" was promulgated. This common rule was developed by the interagency Human Subjects Coordinating Committee and applies to federal agencies involved in human experimentation. The "Common Rule" was published as Department of Health and Human Services 45 CFR Part 46 in the *Federal Register*; June 18, 1991;56(117):28003-28032. Vulnerable populations listed in these regulations include children, prisoners, pregnant women, mentally disabled persons, and educationally or socially disadvantaged groups.

10 US Department of Health and Human Services, National Institutes

of Health, Office for Protection from Research Risks. *Protecting Human Research Subjects: Institutional Review Board Guidebook*. Washington, DC. US Government Printing Office, 1993. Some other special classes that OPRR considers for additional safeguards, but not specifically mentioned in the "Common Rule," are: traumatized and comatose patients, terminally ill patients, elderly/aged persons, minorities, students, employees, and normal volunteers.

11 Special characteristics of patients in VHA facilities that might render them more vulnerable for the purposes of participation in research are discussed in Levine RJ, Lebacqz, K. "Some Ethical Considerations in Clinical Trials." *Clin Pharmacol Therapeutics* 1979; 25:728-741 and in McGuire, ER. "The Entitlement of Veterans Affairs Medical Patients to Vulnerable Population Status for Human Medical Research." *Health Matrix* 1992;2(259):259-301.

12 Additional guidelines for conduct of this type of research are National Alliance for the Mentally Ill. "Policies on Strengthened Standards for Protection of Individuals with Severe Mental Illnesses Who Participate as Human Subjects in Research." Arlington, VA; National Alliance for the Mentally Ill, February 14, 1995; American College of Neuropsychopharmacology. "Surrogate Consent and the Incompetent Experimental Subject," *Food Drug Cosm LJ* 46:739-771; and Berg JW. "Legal and Ethical Complexities of Consent with Cognitively Impaired Research Subjects: Proposed Guidelines," *J of Law Med and Ethics* 1996;24:18-25. See also footnotes 15, 20, 29 and 30 in this series.

13 Nuremberg Code.

14 Therapeutic misconception is discussed in the following: DeRenzo EG. "The Ethics of Involving Psychiatrically Impaired Persons in Research." *IRB* Nov-Dec 1994;7-11; Appelbaum PS, Roth LH, Lidz C. "The Therapeutic Misconception: Informed Consent in Psychiatric Research." *International Journal of Law and Psychiatry* 1982;5:319-329; Appelbaum PS, Roth LH, et al. "False Hopes and Best Data: Consent to Research and the Therapeutic Misconception." *Hast Cent Rep* 1987;17(2):20-4; Bamberg M,

Budwig N. "Therapeutic misconceptions: When the voices of caring and research are misconstrued as the voice of caring." *Ethics and Behavior* 2(3):165-184.

15 The notion of consent auditors has been around a long time, but they have been infrequently utilized. IRB's are permitted to send an observer at any time to evaluate the consent process. This issue is discussed further by DeRenzo in the paper cited in footnote 14 and in Keyserlinigk EW, Glass K, Kogan S, et al. "Proposed Guidelines for the Participation of Persons with Dementia as Research Subjects." *Perspectives in Medicine and Biology* 1995;38(2):319-360.

16 Some of the important issues in consent are discussed in these papers: DeRenzo E. "Surrogate Decision Making for Severely Cognitively Impaired Research Subjects: The Continuing Debate." *Cambridge Q Healthcare Ethics* 1994;3:539-548; Lane LW, Cassel CW, Bennett W. "Ethical Aspects of Research Involving Elderly Subjects: Are We Doing More Than We Say?" *J Clin Ethics* 1990;1(4):278-286; Wichman A, Sandier A. "Research Involving Subjects with Dementia and Other Cognitive Impairments: Experience at the NIH and Some Unresolved Ethical Considerations." *Neurology* 1995;45:1777-1778.

17 Drane J. "The Many Faces of Competency." *Hast Cent Rep* l985(15);17-21. The sliding scale of competence is also discussed in: Buchanan AE and Brock DW. *Deciding for Others: The Ethics of Surrogate Decision Making*. New York: Cambridge University Press, 1990.

18 VHA Handbook 1004.1, August 1, 1996, "Informed Consent."

19 Other ethical issues are discussed in Fulford KWM, Howse K. "Ethics of Research with Psychiatric Patients: Principles, Problems and the Primary Responsibilities of Researchers." *J Med Ethics* 1993;19:85-91.

[20] American College of Physicians. "Position Paper: Cognitively Impaired Subjects" *Ann of Intern Med* Nov 15, 1989;111(10):843-848.

[21] The term "Ulysses Contract" refers to the ancient Greek myth in which the ship captain Ulysses requests his crew to tie him to the mast and ignore his demands for release so that he can listen to the Siren's song without endangering himself or his ship. In the past this has referred to a document that psychiatric patients have executed consenting to anticipated future involuntary treatment. A number of useful references are provided by DeRenzo (see footnote 14) for this type of document in the clinical care setting as well as the research setting. Advance directives for research are also discussed in the American College of Physicians position paper, p. 844 (see footnote 20).

[22] VHA, M-3, Part I, Chapter 9, "Requirements for the Protection of Human Subjects." p. 9-10.

[23] *OPRR Guidebook*, p. 6-30.

[24] VHA, M-3, Part I, Chapter 9, "Requirements for the Protection of Human Subjects." p. 9-10.

[25] These guidelines are clearly set out by OPRR in the *IRB Guidebook* and international codes of conduct. A helpful resource is a detailed and thoughtful table cross-referencing a list of general, scientific, and ethical considerations for human subject research in Sutherland HJ, Meslin EM, Till JE. "What's Missing from Current Clinical Trial Guidelines? A Framework for Integrating Science, Ethics and the Community Context." *J Clin Ethics* 1994;5(4):297-302.

[26] Personal communication, David Wendler, February 1996.

[27] VHA, M-3, Part 1, Chapter 9, "Requirements for the Protection of Human Subjects" policy states, "Incompetent people will not be subjects of research which imposes a risk of injury unless that research is intended to benefit the subject and the probability of benefit is greater than the probability of harm."

[28] As defined by OPRR in the *IRB Guidebook*, p.G-8, "A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

[29] US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *Report and Recommendations: Research Involving Those Institutionalized as Mentally Infirm*. Washington, DC: US Government Printing Office, 1978 and *Report and Recommendations: Research Involving Children*. Washington, DC: US Government Printing Office, 1977.

[30] American College of Physicians. "Position Paper: Cognitively Impaired Subjects." p. 845. NIH Clinical Center. Medical Administrative Series No.87-4. "Consent Process in Research Involving Impaired Human Subjects." March 30, 1987.

[31] American College of Physicians. "Position Paper: Cognitively Impaired Subjects," p. 846.

[32] NIH Clinical Center. "Consent Process in Research Involving Impaired Human Subjects." March 30, 1987.

[33] Jonas H. "Philosophical Reflections on Experimenting with Human Subjects." *Daedalus* 1969;98:219-247.

[34] *OPRR Guidebook*, p. 3-39 through 3-41.

[35] The following references give an overview of the discussion about the use of placebos. Lasagna L. "The Helsinki Declaration: Timeless Guide or Irrelevant Anachronism?" *J Clin Psychopharm* 1995; 15(2):96-98; Tuabes G. "Use of Placebo Controls in Clinical Trials Disputed." *Science*, 1995;267:25-26; Rothman KJ, Michels KB. "The Continuing Unethical Use of Placebo Controls." *N Engl J Med* 1994;331:394-398; (A series of letters in response to the Rothman paper were published in the Jan. 5, 1995, issue of the *New England Journal of Medicine*).

[36] Leber PD. "Hazards of Inference: The Active Control Investigation." *Epilepsia* 30(suppl)1989;S57-S63; Leber PD. "Is There an Alternative to the Randomized Controlled Trial?" *Psychopharm Bull* 1991;27:3-8; De Deyn PP. "On the Ethical Acceptability of Placebo Application in Neuropsychiatric Research." *Acta Neurol Belg* 1995;(95):8-17.

[37] Burt RA. "The Suppressed Legacy of Nuremberg." *Hast Cent Rep* Sept-Oct 1996;26(5):30-33.

[38] VHA, M-3, Part 1, Chapter 9, "Requirements for the Protection of Human Subjects."

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9. Ethics Consultation on Certain Questions of Enrollment

Introduction

Recent Federal legislation, Public Law (P.L.) 104-262, the "Veterans Health Care Eligibility Reform Act of 1996," authorized a major revision of eligibility criteria that govern access to health care provided by the Veterans Health Administration (VHA). For the first time, all veterans receiving care in VHA will have equal eligibility for all health care services offered in a universal benefits package, whether these services are provided on an inpatient or outpatient basis. This change should foster more effective and efficient provision of services in the most appropriate care setting.

Another change mandated by P.L. 104-262 is that VHA must establish and operate a system of annual patient enrollment. The law gives an enrollment priority that closely follows, but does not replicate, current eligibility criteria. The law defines six priorities of eligible veterans who, if they seek care, shall be enrolled. In this report, these individuals are described as "mandatory" patients and applicants. The law defines a seventh priority of eligible veterans who, if they seek care, may be enrolled. They are described as "optional" patients and applicants. Beginning October 1, 1998, VHA will be permitted to provide care only to enrolled patients (with certain exceptions provided in the law; see Appendix A for pertinent points of current enrollment legislation).

In view of the significant changes brought about by P.L. 104-262, and of the future possibility that demand for VHA health care might exceed available resources to responsibly provide care, the VHA Bioethics Committee was charged with addressing the following ethical issues and questions related to enrollment:

1. Establish a model for ethical decision making about enrollment that is principle based.
2. Utilize this model to provide an ethical framework for making decisions regarding additional prioritization of veterans for enrollment within the priorities, and for possible disenrollment of already enrolled groups or individuals.
3. Is there an ethical obligation to maintain uniformity of enrollment and disenrollment prioritization criteria across the system?
4. What is the VHA obligation to the veterans who are difficult to reach for purposes of enrollment, e.g., the chronically mentally ill, the homeless? How far is VHA ethically obliged to go to locate these individuals, provide information about enrollment, and actually offer them a convenient mechanism for enrollment separate from mechanisms for all other groups?

In implementing enrollment, it is anticipated that conflicts between claims of some veterans for access to care and responsibilities of VHA to enrolled patients will arise. As a response to the charge, the committee presents a discussion that considers: a) moral values implicit in the law; b) who has legitimate access to VHA health care; c) what responsibilities VHA has to patients; and d) whether VHA may choose not to enroll some eligible veterans who seek care. The committee proposes a balance of claims and responsibilities that addresses these issues and that can guide VHA in complying with the legally required enrollment priorities in an ethical manner.

Response to the Charge

1. Establish a model for ethical decision making about enrollment that is principle based.

A "model" of decision-making based on principles is a presentation that: a) introduces the ethical values put into play by an action; b) identifies conflicts; c) justifies a hierarchy of values; d) poses discussions of the conflicts; and e) advises an ethically defensible course of action. The model developed in this report identifies principles and values of enrollment, and it clarifies ethical conflicts anticipated in the practice of enrollment. The model then stipulates a ranking of values that helps address the conflicts, followed by discussion and recommendations.

VHA faces a possible problem of having to deny enrollment to some eligible veterans who seek care. The two most general variables put into conflict in this problem are "individuals' access to care" and "responsibilities of providing care to enrolled patients." On the one hand, these variables converge in the mission to grant access to as many eligible veterans who seek care as for whom VHA can responsibly provide it. On the other hand, they possibly conflict in the realization that more eligible veterans might seek care than VHA can responsibly serve. *The committee stipulates that enrolled patients deserve responsible care.* Therefore, in a conflict between the values that justify providing access to eligible individuals and the values of providing care responsibly to enrolled patients, the committee thinks that latter values take precedence, and preserving them warrants denying access to some eligible individuals.

To outline such decision-making, the committee presents three guiding principles, two sets of values, and several criteria for attempting to resolve conflicts between the values.

- First, general ethical principles of justice, equality, and fairness express priorities that should be respected in considering individuals for enrollment and in responsibly providing care to all enrolled patients. These principles are the building blocks of subsequent values.

- Second, values that support enrolling individuals include loyalty, obedience to law, service-connection, and rescue. These values point toward, but do not finalize, who should be enrolled. They are mute on who should be denied enrollment.
- Third, values that indicate responsible provision of care include contract, continuity of care, security, beneficence, quality, fiscal integrity, equity, stewardship, and efficiency. They convey the contents of responsible care to enrolled patients.
- Fourth, some criteria for attempting to resolve conflicts between the values of granting access and the values of providing responsible care include need, non-abandonment, right, entitlement, merit, ability to pay, lottery, and first come/first served. These criteria are defined and briefly discussed in Appendix B.

Discussion

Moral "values" express prospects of action that are thought to be right, good, or desirable, e.g., that individuals should have access to health care or that providers should have responsibilities to patients. "Principles" express reasons for supporting some values, e.g., that access to health care is a matter of "justice" or that responsibilities to patients are matters of "fairness." "Ethical issues" arise when a course of action, such as enrollment, signals a possible conflict of values. An "ethical" response to issues consists in relating, ranking, and deciding between the pertinent values in order to make a coherent and plausible recommendation for bridging the conflict. In this report, the committee presents a model of ethical reasoning that concludes that eligible veterans who seek care should be enrolled and re-enrolled, unless at some point these actions threaten VHA's responsibilities to some other already enrolled patients.

In this context, "denial of enrollment" can encompass any of the following kinds of actions (not all of which are ethically justifiable): a) disenrollment of enrolled patients during an enrollment period; b) refusal of re-enrollment to enrolled patients at the time of annual enrollment; or c) refusal of enrollment to new applicants at the time of annual enrollment.

General Ethical Principles

Justice

Individual veterans are unique persons with differing claims to receive health care from VHA. In planning enrollment, VHA must rank individuals' claims, as well as its responsibilities in meeting them. Justice is the principle that most generally legitimates these rankings. Justice expresses the values that eligible veterans are ethically due to receive health care from VHA, and that VHA is ethically obligated to provide care responsibly. Distributive justice suggests criteria for limiting access if, and only if, all patients deserving of care cannot be responsibly cared for (see Appendix B).

Equality

Respect for justice yields another general ethical principle, equality. The ethical principle of equality expresses a value of access, that all eligible veterans who seek care should receive consideration. It also expresses values of providing care responsibly, i.e., all enrolled patients have access to a similar level and quality of care and that similar kinds of applicants be universally enrolled or universally not enrolled.

Fairness

Respect for equality yields a third general ethical principle, fairness. The ethical principle of fairness expresses the value that veterans' different claims, and VHA's several responsibilities, be consistently, not capriciously, considered. Regarding access, fairness is reflected in the distinction between optional and mandatory enrollees and in the higher ranking of mandatory patients. Regarding responsibilities, those of equity, stewardship, and efficiency exemplify fairness.

Justice, equality, and fairness by themselves do not determine what care is due, to whom care is due, or how to consistently prioritize for care. Additional, more concrete ethical values are necessary to help make those assessments. Nonetheless, respect for justice, equality, and

fairness underlie VHA's attempt to achieve an ethical enrollment process, and also legitimate the more concrete values to which this report now turns.

Values Justifying Access to Care

Loyalty

Loyalty supports enrolling eligible veterans who seek care. Veterans expressed loyalty to the United States by serving in the Armed Forces and risking unique harms. In return, eligible veterans may receive defined health care. The value of loyalty is marked by veterans' beliefs that promises will be kept, by VHA's making good on the promise of care, and by the commonly held trust that VHA will put the needs and interests of patients first.

In this context, claims of loyalty might be controversial because some veterans believe that they are eligible for care in VHA based on promises made to them during their time in the Armed Forces. While VHA will be able to provide care only according to the new enrollment criteria, the system should acknowledge that some veterans who cannot qualify for a mandatory enrollment category nonetheless truly believe that they have been promised lifelong access to care in VHA.

Obedience to Law

Because VHA is a part of the Federal government and provides health care largely with appropriations from Congress, compliance with Federal law is a governing value of VHA. VHA must follow congressional mandates and may not ignore or deviate from them. The force of this value is that VHA must follow the directions of P.L. 104-262 in enrolling eligible veterans who seek care, and that VHA may create "subpriorities" of patients within the legislated enrollment priorities. The value of obedience voices that VHA is obligated to apply the law, not that the law is in all parts ethically justifiable. VHA should seek relief from Congress with appropriate documentation if it encounters legal requirements that elude ethical justification.

Service-Connected Need

The value of service-connected need reflects the acknowledgment that the injuries, illnesses or disabilities of some veterans are caused or aggravated by military service. This value conveys two priorities at the heart of VHA's historical mission, that eligible veterans with service-connected disabilities have stronger claims to receive care than those without service-connected disabilities, and that eligible veterans with greater service-connected disability have stronger claims than those with lesser degrees of disability. Finally, the credibility of this value depends upon consistent application of disability rating regulations, as well as periodic assessment of determinations.

Rescue

The value of rescue addresses VHA's historical commitments of providing emergency care to veterans, health care to poor veterans, and back-up emergency health services during times of war and disasters. In these several contexts, rescue expresses the priority of meeting the needs of especially vulnerable individuals and communities. P.L. 104-262 acknowledges the value of rescue in saying that VHA may provide care for non-enrolled eligible veterans who have "compelling medical need."

Values of Providing Responsible Care

Contract

Contract is a central guiding value of providing responsible care. P.L. 104-262 gives VHA instructions for developing an enrollment contract. Contract conveys a binding agreement between identified parties. Contracts offered should be fulfilled, and contracts that cannot be fulfilled should not be offered. Contract also signals VHA's "fiduciary responsibilities." American law views health care providers as fiduciaries of patients. In the fiduciary relationship, a party with particular needs, interests, preferences, and vulnerabilities (e.g., an enrolled veteran) contracts with a party with the competence, power, and willingness to provide particular goods and/or to protect from

particular harms (e.g., VHA). Health care fiduciaries accept responsibilities for matters such as professional competency, advocacy, respect, truthtelling, confidentiality, and putting patients' interests first. Additionally, respect for the value of contract necessitates that veterans who seek care be informed of the details of enrollment, including possibilities of denial and disenrollment, and that they consent to be enrolled.

Claims of contract as a value should be distinguished from the legal definition of contract, which necessitates a mutuality of obligation on the part of the contracted parties and a legal recourse available in the event of non-performance on the part of any party. For example, after being enrolled, a veteran may pursue legal action against VHA for non-provision of necessary care. VHA, however, has no legal recourse to force an enrolled veteran to keep medical appointments, take prescribed medications, or comply with any medical recommendations.

Security

The value of security directs that enrolled patients not be disenrolled; that patients seeking re-enrollment be accommodated; and that applicants who seek care not be denied enrollment without good reasons. Disenrollment, meaning denial of care to enrolled veterans during an enrollment period, cannot be ethically justified and should not be done. All denials of enrollment or re-enrollment should be scheduled to take effect only at the end of an enrollment period. Furthermore, the only ethical justification for these denials is that retaining or accepting some individuals prevents VHA from meeting its responsibilities to enrolled patients with stronger claims to care. VHA should counsel denied individuals about access to other health care providers and assist them in receiving it.

Continuity of Care

Continuity of care is a professional value that conveys that VHA should not break therapeutic relations with current patients. Disenrollment during an enrollment period violates both professional

standards and patients' best interests. Some denials of enrollment and re-enrollment risk the same.

Beneficence

The value of beneficence expresses the priority of doing good in providing health care. The general goods that health care professionals should provide include preserving patients' lives, protecting against new harms, providing palliative care (end-of-life and otherwise), and promoting individual and collective health and well-being. VHA's mission emphasizes the specific good of providing rehabilitative care for veterans. Beneficence suggests doing all these goods. If all cannot be done, then beneficence requires VHA to prioritize them in accordance with the organization's mission, patients' expectations, professional and legal requirements, and limited resources.

Quality

The value of quality directs that VHA provide care according to professional standards, patients' expectations, and legal requirements. Quality expresses the priority that VHA remain a reliable health care provider, one worthy of trust by patients and professionals.

Fiscal Integrity

Fiscal integrity expresses the value that VHA receive a sufficient budget and stay within it. Possible negative consequences of violating fiscal integrity include postponement or non-provision of necessary care for enrolled patients.

Equity

The value of equity directs that patients have access to the same services regardless of their location in the system, and that enrollment be uniformly enacted throughout the system. The committee presumes that the 22 Veterans Integrated Service Networks (VISNs) will play a central role in enrollment. Equity expresses the priority that eligible veterans not be unfairly privileged or penalized by differences between levels of care or between enrollment practices among the VISNs.

Stewardship

Stewardship directs that VHA's fixed dollars be allocated adequately throughout the system to meet each VISN's different needs for providing care. Operationalization of this value requires knowledge of numbers of enrolled patients, their geographic distribution, and their diagnoses and typical costs. From an ethical standpoint, the decision about services that will be offered in the universal benefits package is a decision about stewardship of resources, because the contents of the package will define VHA's clinical commitments to enrolled patients, and the extent of the package will influence VHA's ability to meet all of its responsibilities. Stewardship additionally directs that VHA's fixed dollars be spent on patient care, education, research, and employment, and other activities that support and enhance the delivery of care.

Efficiency

The value of efficiency directs that dollars be spent as prudently as possible throughout the system. Some commitments of mission and quality include costs that cannot be repeatedly reduced. Efficiency should be continuously sought. It can be meaningfully measured, as controllable and non-controllable costs are distinguished, and as inefficient laws, policies and practices, excess capacity, replication of services, waste, and futile care are reduced.

2. Utilize this model to provide an ethical framework for making decisions regarding subprioritization of veterans for enrollment within the priorities, and for possible disenrollment of already enrolled groups or individuals.

Priorities and Subpriorities

Assumptions

There are several key points that shape the committee's reply to this part of the charge.

- The committee realizes that enrollment is a temporal, dynamic, and evolving process that will not conform exactly to a model of ethical decision-making. For example, the eligibility priority in

P.L. 104-262 is ethically significant, and the committee utilizes it in replying to this part of the charge. But the committee considered that in actually enrolling patients throughout the system, VHA probably, and for very good reasons, will initially enroll many individuals on a first come/first served basis, rather than try to schedule enrollment according to the legal eligibility priority. The general point here is that while discussion of a model of ethical values might appear static, the committee realizes that operationalization of enrollment is a complex process that requires applied ethical decision-making, not automatic referral to ethical formulae. Thus, this report's recommendations are forwarded as enrollment guidelines and timelined targets, not as initial necessary conditions.

- An enrollment system must be established by October 1, 1998. The committee presumes that VHA will gain valuable experience as the system becomes operational and will apply what is learned in meeting future needs. Therefore, the report includes discussion of ethical issues of enrollment before and after October 1998.
- The committee distinguishes mandatory and optional "current patients," and mandatory and optional "new applicants." Current patients are defined as eligible veterans who have received care from VHA in the three years preceding the first enrollment deadline. After that deadline, current patients are defined as enrolled veterans. New applicants are defined as eligible veterans who have not received care in the past three years and seek care before the first enrollment deadline. After that deadline, new applicants are defined as eligible veterans who are not enrolled and seek care.
- In developing its recommendations, the committee could not reach consensus on one point: the ethical legitimacy of creating subpriorities in the legally mandatory enrollment Priorities 5 and 6, and possibly denying enrollment to some new applicants in these two priorities. The discussion of broad ethical concerns about enrollment that emerged in consideration of these matters appears in Appendix C of this report.

Recommendations

The committee makes seven unanimous recommendations:

1. No enrolled patients should be disenrolled during a defined enrollment period.
2. Enrollment of all mandatory veterans who seek care should be always attempted.
3. No enrolled mandatory patient who seeks to have care continued at the time of annual enrollment should be denied re-enrollment.
4. Enrollment may be limited to mandatory eligible veterans who seek care. Optional eligible veterans may be denied enrollment or re-enrollment.
5. Denial of enrollment or re-enrollment of all optional eligible veterans should be strongly considered before denying any mandatory eligible veteran.
6. No eligible veteran who seeks care should be denied access if and when a VHA facility is the only local provider of particular medical services needed by an individual.
7. VHA must provide counseling regarding access to other health care providers and assistance in receiving it to any veteran denied enrollment or re-enrollment.

Discussion

As previously stated, VHA's patients deserve responsible care. The values presented as marking of this care may be read as an index of responsibilities to enrolled patients. Therefore, as a practical guideline, VHA may manage enrollment by enrolling and re-enrolling only as many individuals as can be responsibly cared for, and by denying enrollment and re-enrollment to some eligible veterans if, and only if, these denials are necessary to preserve responsibilities to enrolled patients.

The principle of justice gives two broad justifications for these claims. First, it is unjust to enrolled patients to admit or retain more

individuals than can be responsibly cared for. Second, it is unjust to applicants, even to deserving applicants, to admit them to a challenged system. Equality and fairness, as expressed through equity, stewardship, and fiscal integrity, send the same messages.

Therefore, considering enrollment through October 1, 1998:

- The values of contract, continuity of care, and security, reinforced by all the access values, warrant enrolling all legally mandatory current patients who seek care.
- P.L. 104-262 authorizes VHA to create subpriorities within the six mandatory priorities, and one purpose of creating subpriorities could be to establish criteria for denying enrollment to some mandatory individuals. However, the law requires VHA to accept all individuals in the first three priorities, as does the value of beneficence, reinforced by the access values of service-connection and rescue. The committee thus recommends against creating subpriorities within the first three mandatory priorities and enrolling all current patients and new applicants in these priorities who seek care.
- As previously mentioned, some criteria typically considered for restricting access include need, non-abandonment, right, entitlement, merit, ability to pay, lottery, and first come/first served. The committee recommends that VHA not utilize any of these criteria to create subpriorities in mandatory Priority 4, because the needs of these individuals are too great to refuse any of them enrollment. All Priority 4 current patients and new applicants should be enrolled.
- The committee could not reach consensus about creating subpriorities within Priorities 5-6. Members agreed that the reason for attempting this additional prioritization is that denial of enrollment of some of these mandatory new applicants might be necessary to preserve the provision of responsible care to already enrolled patients.
- Turning to optional current patients and new applicants, several ethical values combine to warrant enrolling all who seek care.

However, respect for the absolute priority of meeting responsibilities to current and future mandatory enrollees justifies at least considering not enrolling current optional patients, and more strongly considering not enrolling new optional applicants. Some current optional patients should be enrolled if they want to be, for example, individuals who are seriously ill, actively involved in ongoing treatment, or being evaluated for eligibility for a mandatory priority. Any optional individual who is enrolled should be fully and clearly informed of the possibility of future refusal of re-enrollment. Optional individuals who seek care and are denied enrollment or re-enrollment should be counseled by VHA regarding access to other health care providers and assisted by VHA in gaining that access.

Regarding enrollment after October 1, 1998:

- VHA should annually re-enroll all mandatory current patients who seek re-enrollment, as warranted by contract, continuity, security and equity, and reinforced by loyalty, service-connection, and rescue.
- VHA should annually enroll all new applicants in Priorities 1-4 who seek care.
- For reasons discussed above, the committee could not reach consensus about universally enrolling mandatory new applicants in Priorities 5-6.
- VHA should adopt an equitable stance toward re-enrolling current optional patients and enrolling optional applicants. In one scenario, VHA could re-enroll and enroll optional individuals and still meet its responsibilities to mandatory patients. In another scenario, optional individuals could be refused re-enrollment and enrollment because VHA could not meet its responsibilities to mandatory patients and also provide care to optional patients.

An Ethical Postscript

The guidance over time of this report's model for ethical decision

making can be plainly stated:

a. do not break therapeutic relationships during the time for which they are promised;

b. existing mandatory relationships (with some legal exceptions) take precedence over mandatory ones not yet established;

c. keep mandatory relationships that are begun, unless patients or legitimate surrogates discontinue them;

d. always preserve the values necessary for responsible provision of care;

e. do not begin, or do not promise to renew, optional therapeutic relationships;

f. always assist veterans denied enrollment or re-enrollment in making a successful transition to other providers in their communities.

The committee could not reach consensus on the following guideline:

g. do not begin some mandatory relationships that, once begun, would undermine the values necessary for responsible provision of care.

3. Is there an ethical obligation to maintain uniformity of enrollment and disenrollment prioritization criteria across the system?

The committee replies to this question in the positive. Recognizing that enrollment will initially be a temporal, dynamic, and evolving process, the committee recommends equity of access as a temporal target, not as an initial necessary condition.

Discussion

The principle of equity directs that enrollment and re-enrollment be uniformly enacted throughout the system. Equity expresses the absolute value that similarly needy eligible veterans not be privileged or penalized by geographic differences between enrollment practices in the

system. Such privileges and penalties would violate fairness, and render loyalty, rescue, contract, continuity, and security arbitrary and capricious. They would undermine VHA's fiscal integrity, stewardship of resources, and efficiency.

Prior to the first enrollment deadline, a plurality of enrollment strategies is tolerable as a necessary part of gaining experience, information and data, particularly data about the geographical distribution of mandatory and optional patients throughout the system. After the first deadline, however, VHA should identify a target date after which equitable enrollment is required systemwide. With prospective and capped budgets, VISNs have a real economic incentive to conduct enrollment in the most cost-effective manner. To counter this incentive with the value of realizing equitable enrollment, VHA should direct that each VISN may enroll only patients in priorities from which all VISN's are enrolling, and all VISNs must enroll patients in priorities from which any VISN is enrolling. VISNs should not receive funding-driven incentives to enroll less costly patients, or funding-driven penalties for enrolling more costly ones. Similarly, if VHA gains capacity to retain revenues from other payers, VISNs should not enroll lower priority paying patients ahead of higher priority patients covered solely by allocated funds. Finally, for VHA to reach equitable provision of care, all enrolled patients must have access to similar services, and similarly sick patients must be offered similar care.

The first major difficulty in realizing the value of equity could arise in facing the question of enrolling and re-enrolling optional veterans who seek care. Each VISN will be adequately funded to care for its mandatory enrollees. One VISN could conceivably realize the value of efficiency by bringing care for its mandatory patients in under budget, and then cite this value as justification for also enrolling optional veterans. However, another VISN, with different costs, could perform efficiently and bring its care for its mandatory patients in at budget, and then cite this value as justification for not also enrolling optional patients. Whether and how to permit similarly efficient VISNs with different costs of caring for mandatory patients to enroll optional patients is a question VHA could face in attempting system-wide equitable enrollment of optional veterans.

4. What is the VHA obligation to the veterans who are difficult to reach for purposes of enrollment, e.g., the chronically mentally ill, the homeless? How far is VHA ethically obliged to go to locate these individuals, provide information about enrollment, and actually offer them a convenient mechanism for enrollment separate from mechanisms for all other groups?

VHA has ethical responsibilities to reach out to these eligible veterans. Some chronically mentally ill and/or homeless veterans might have both greater need and less ability to initiate or complete an enrollment process without assistance. Many individuals might qualify as mandatory patients and, therefore, would have higher priority for enrollment than some more easily enrollable optional individuals.

VHA should utilize its own existing methods for locating these veterans, i.e., standdowns, Vet Center programs. Those individuals who qualify should be enrolled if they want to be. Impaired decision-making on the part of some of these veterans should be anticipated and provisions for attaining legitimate surrogate decision-makers planned.

Discussion

The values underlying this response include loyalty, service-connected need, and in some situations rescue and beneficence. Veterans, including currently vulnerable groups such as the chronically mentally ill and the homeless, expressed loyalty to the United States by serving in the Armed Forces and risking unique harms. The United States, through VHA, should stand loyal to these eligible veterans by providing necessary health care.

The illnesses suffered by these veterans, i.e., mental illness and illnesses and disabilities that contribute to homelessness, might have been resultant from or aggravated by military service. Veterans with service-connected disabilities have the strongest claims to receive health care from VHA. VHA has already recognized this special component of its mission by establishing outreach programs for mentally ill and homeless veterans. These programs should be strengthened as one effective means of better connecting with these veterans for purposes of enrollment.

Rescue expresses the value of meeting the needs of especially vulnerable individuals. Chronically mentally ill and homeless veterans are among the most vulnerable because of their continuous need for medical treatment and of the difficulties of sustaining their health while impoverished.

Lastly, beneficence expresses the value of doing good in providing health care. Strengthening outreach to enhance enrollment of these vulnerable veterans is consistent with another special component of VHA's mission, that of providing rehabilitative care for injured or disabled veterans, as well as with the general goods of preserving life, protecting against harm, and offering relief and respite from some of life's most threatening circumstances.

Appendix A: A Selective Summary of Current Enrollment Legislation

P.L. 104-262 requires VHA to enroll certain eligible veterans who seek care: mandatory patients within priorities. It permits VHA to enroll additional eligible veterans who seek care: optional patients. It designates annual enrollment as a necessary condition for providing and receiving health care with the following exceptions. Treatment without enrollment can occur for: 1) any service-connected (SC) veterans for treatment of a SC condition; 2) any condition of a SC veteran with 50% or greater disability; and 3) veterans released or discharged for a disability incurred or aggravated in the line of duty for the 12-month period following discharge or release from active duty.

The enrollment priorities are listed below in order of precedence. Priorities 1-6 correspond to "mandatory" patients. Priority 7 corresponds to "optional" patients.

1. Veterans with service connected (SC) disabilities rated 50% and above;
2. Veterans with SC disabilities rated 30% or 40%;
3. Former POWs, veterans with SC disabilities rated 10% or 20%, veterans discharged from Active Duty for compensable conditions, and veterans awarded special eligibility classification under Section

1151 (disability caused by or secondary to medical treatment provided by VHA);

4. Veterans who are in receipt of aid and attendance or housebound benefits and other veterans who are catastrophically disabled;
5. Non-SC veterans and 0% SC veterans unable to defray the expense of health care, including Medicaid recipients, VA pensioners, and veterans with incomes below established means test thresholds;
6. All other eligible veterans who are not required to make copayments for care including: WWI and Mexican Border War veterans, veterans receiving care for exposure to toxic substances or environmental hazards, and compensable 0% SC veterans who do not meet VA's means test;
7. Non-SC veterans and non-compensable 0% SC veterans able to defray the expense of health care (annual income and net worth above the means test thresholds), i.e., historical Category "C" patients.

Additional Pertinent Points

1. VHA is permitted to establish enrollment priorities within each one of these priority groups.
2. VHA is permitted to make enrollment exceptions to these priorities for "compelling medical reasons."
3. VHA must establish a system for enrollment by October 1, 1998.
4. VHA may not provide care to non-enrolled veterans after that date.

   There are three exceptions to this rule prohibiting care to non-enrolled veterans:

   a. veterans in need of care for a service-connected condition;
   b. veterans with disabilities rated 50%+ service-connected;
   c. veterans discharged or released from active duty for a 12-month period following separation for a compensable disability incurred or aggravated in the line of duty.

5. The law makes mention of four medical conditions: spinal cord dysfunction, blindness, amputations, and mental illness. VHA must provide "reasonable access to care and services for those specialized needs," and must retain at least current system-wide capacity to provide these services for patients who want them.
6. Regarding veterans suffering from exposure to ionizing radiation (IO), herbicides in Vietnam (HV), and toxic substances in the Gulf War (GW), specific, limited, required care is stipulated for each of these types of patients. Also, particular enrollment deadlines are given for HV veterans and GW veterans, and individuals in these groups who are enrolled before these deadlines must be continued in care after the deadlines.
7. The prioritizing of 0% SC veterans in need of care for non-SC illnesses, injuries, or conditions as "optional" weakens the access of a significant number of veterans for whom VHA previously was required to provide care.
8. Patients in Priority 7 must make a co-payment. Veterans in Priorities 6 and 7 may take a means test and move into Priority 5 if qualified.
9. VHA may design and provide a benefits package for all enrolled veterans that includes primary and preventive care, as well as care for illness, injury, or condition regardless of service connection.
10. The law expects VHA "to the extent feasible, [to] design, establish and manage health care programs in such a manner as to promote cost-effective delivery of health care services in the most clinically appropriate setting" (1706.a).
11. VHA may provide care "effective in any fiscal year only to the extent and in the amount provided in advance in appropriations Acts for such purposes" (1710.4).

Appendix B: Some Criteria for Restricting Access to Health Care

It is not clear whether all mandatory new applicants in Priorities 5-6 can always be enrolled. Distributive justice offers several criteria for deciding about limiting access to care: need, non-abandonment, right, entitlement, merit, ability to pay, lottery, first come/first served. To briefly consider the issues at stake, the committee defines and briefly discusses these criteria. One or more of them might serve as a basis for denying access to some mandatory new applicants in Priorities 5-6 if, and only if, such restriction of access is one necessary means of preserving responsibilities to enrolled patients. All of these criteria encapsulate decisional priorities, and each favors some priorities and discounts others. In the discussion each criterion is briefly explained and evaluated. None is urged as decisively preferable from an ethical standpoint.

Need

Need can refer to individuals' needs for particular medical treatments, and to their need for access to health care. The strength of need as a criterion for restricting access is that it prompts providers to identify and rank different generic needs. For example, VHA could decide that the need of all mandatory new applicants in Priorities 5-6 for access to health care ranks higher than some of the particular medical needs of any enrolled patients. This ranking of generic needs would warrant granting access to health care to all mandatory new applicants, but also limiting the medical treatments available to patients. Or, thinking in reverse, VHA could decide that provision of treatments for most medical needs of most enrolled patients ranks higher than the need of mandatory new applicants for access to health care. This ranking would warrant development of a "category of illness" that would govern admission of individuals into the system. In this way lies complexity, because adoption of a "category of illness" itself requires judgment. Should VHA prioritize less severe conditions and thereby more likely help a greater number of individuals who have comparatively less medical need? Or should VHA prioritize more severe

conditions and thereby more likely help fewer individuals who have comparatively greater medical need? These are only a few of the vexing questions VHA may encounter in trying to utilize need as a basis for denying access to some mandatory new applicants in Priorities 5-6.

Non-abandonment

Non-abandonment encapsulates the priority that institutional and clinical providers not discontinue the access of current patients. This criterion is therefore possibly not applicable in thinking about denying access to some mandatory new applicants in Priorities 5-6 because all of these veterans are applicants, not current patients. Denying some of them access would therefore not be abandonment. However, as all these veterans are "mandatory" new applicants, they may be plausibly said to have undeniable access to VHA, and if so, then denial would be abandonment. Notably, even if one of these two interpretations would be made, that would not settle which among all applicants with the same claim to access should be denied.

Right and Entitlement

Rights are human, moral, and legal powers possessed by citizens in societies. The power of rights is familiarly expressed in at least three ways: a) the right to be left alone in living one's life (non-interference); b) the right to receive some particular goods, for example, necessary medical care and access to health care (positive rights); and c) the right to be treated fairly in adjudication of conflicts of rights (due process). Entitlements are defined goods granted to particular populations by a legislature, e.g., Medicare for America's elderly and Medicaid for America's poor. While rights and entitlements are important, access to VHA health care is not granted as a right or an entitlement, but rather as a discretionary act of Congress. That fact stated, analogies to rights and entitlements might shed some light on the problem under discussion. Is the "mandatory" status of new applicants in Priorities 5-6 the functional equivalent of an unrestricted right or entitlement to access to VHA? If so, then VHA would probably need explicit approval from Congress to deny access to these mandatory new applicants.

However, if the "mandatory" status of these veterans is more like a restricted right or entitlement, i.e., one dependent upon available funding, then the restriction could count as a justification for denying access to some of them.

Merit

Merit indicates identified worthiness as a basis for restricting access to health care. The current eligibility reform directs VHA to restrict access according to particular recognized merits as described in the eligibility priorities and subpriorities. Therefore, a revised meritocracy would have to be developed and approved in order to deny some mandatory new applicants in Priorities 5-6.

Ability to Pay

Ability to pay signals restricting of access to health care according to a defined dollar amount of income, assets, and insurance. The provider decides the amount and requires individuals who want access to take a "means test." Applicants whose wealth exceeds the defined amount "pass" the means test, and their access is restricted by their ability to pay. Applicants whose wealth is less than the defined amount "fail" the means test, and access is granted to them because of their inability to pay. VHA currently utilizes ability to pay in defining who counts as a Priority 5 eligible veteran, and VHA could use this criterion as a basis for denying access to some mandatory new applicants in Priority 6.

Lottery

Lottery utilizes random selection from a defined group as a basis of restricting access. Lottery is impartial and it would allow VHA to bypass the decisional complexities surfaced by all the other criteria. However, there is strong feeling that it is inhumane to hand over to a lottery something as important in life as access to health care. It may be more preferable to take on difficult decisional complexities than to assign to mere chance the power of denial of access to some mandatory new applicants in Priorities 5-6.

First Come/First Served

To employ the criterion of first come/first served, a provider decides the number of patients that can be accepted for care, then grants access until that number is reached. First come/first served thus centers restriction of access in the choices of individuals to present or not present for care. Like lottery, first come/first served avoids decisional complexities encountered with the other criteria. Unlike lottery, however, first come/first served is not impartial, because individuals are differently informed about the availability of care and differently capable and disposed to come for care. VHA could accentuate the disadvantages that already hinder sicker and less sophisticated veterans by adopting first come/first served as the basis for denying access to some mandatory new applicants in Priorities 5-6.

Appendix C: Ethical Caveats of Enrollment

This appendix summarizes some additional concerns about enrollment that emerged in the committee's deliberation of possibly denying access to some mandatory new applicants in Priorities 5-6.

The committee frankly considered that VHA's future patient population may exceed the current level. The enrollment legislation heightens this possibility, and the prospect of significant increases in the numbers of patients in enrollment Priorities 2, 3, 5, and 6 should not be discounted. The impact of even small increases in the number of Priority 4 patients should be anticipated because Priority 4 figures to include individuals with high-cost health care needs. The prospect of more patients is likely because there are significant numbers of eligible veterans who are not current patients but who could legitimately apply for access to the mandatory priorities. Also, retrenchments by other public and private providers, combined with the attractiveness of VHA's universal benefits package, could motivate eligible veterans who are not current patients to seek enrollment. If VHA is inundated with mandatory applicants, enrollment legislation will have to be revisited and additional ethical consultation will be necessary.

As matters now stand, possible denial of enrollment to any mandatory applicant is complicated. The complication stems from P.L. 104-262. On the one hand, the law clearly identifies eligible veterans to whom VHA must provide care if they seek it. On the other hand, the law clearly holds that care be provided only to the extent and in the amount for which Congress appropriates funds. As this new way of granting access (i.e., enrollment) begins, the question arises: Can VHA refuse enrollment to mandatory eligible applicants based on the system's inability to pay? The committee does not know the answer to this question, but did discuss ways of avoiding it.

1. VHA could lower the income level in the means test, thereby limiting expansion of Priority 5, poor veterans.
2. VHA could offer a lean, scaled-down universal benefits package, thereby prospectively limiting costs of care.
3. VHA can improve operational efficiencies.

None of these options seems satisfactory. A stricter means test would further socially threaten the very veterans and their families already marginalized by poverty or low household incomes. A scaled-down universal benefits package would put quality of care at risk, and also quell the opportunity to legally provide the holistic care that VHA gained in eligibility reform. Efficiencies should be achieved, but 100% efficiency is always an ideal, and the trade-offs of efficiency with priorities of mission, quality, and equity always preclude realization of 100% efficiency.

The committee clarified that even if VHA at some point in the future may legally deny enrollment to some mandatory eligible applicants, the system's inability to pay is not a criterion for deciding which ones to deny. As noted above, the committee reached consensus that all applicants in Priorities 1-4 should be enrolled and all current patients in these priorities be re-enrolled if they want to be. If the numbers and needs of these patients overwhelm resources, VHA should report the situation to Congress. The committee concurred that there are obvious problems with denying access to any mandatory

applicants, for example, that some denied individuals will be sicker and/or poorer than others already enrolled, and that denying some mandatory applicants would at any given time create strong political backlash.

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10. Protection Against "Gag Rules:" Safeguarding Provider-Patient Relationships

Charge

The imposition of managed care principles and techniques can cause deviations and irregularities in standards of practice within the VHA health care system, for example, distortions of clinician-patient relationships, outcomes and costs of care. One example of a managed care practice is the "gag rule" appearing in provider contracts. What are the ethical considerations of "gag rules" for clinicians, and what ethical considerations should guide VHA regarding this organizational practice? The purpose of this report is to focus on this one specific pressure or challenge to professional standards of practice as it may affect VHA practitioners, and to examine the current status of "gag rules" and the associated ethical considerations.

Background

Health care has existed historically in an environment that has offered virtually any potential benefit or prolonged life to health care recipients able to pay for the services under the assumption of unlimited resources. That assumption is increasingly being called into question. Managed care is one expression of that challenge which has profoundly altered the delivery of health care.[1]

The traditional fee-for-service system has not been without its ethical challenges. Over-utilization of some services and rationing on the basis of financial means have occurred. The concept of managed

care is morally neutral and may be used to convey the positive concept of managing the care of a patient in an ethical manner, with the most appropriate treatment to achieve the most beneficial outcome. However, the morality of the concept depends on its intent and the effect on the beneficiaries. The term managed care has increasingly become associated with economics as the ascendant intentional motivation, introducing "the plan" as a decision-making agent and stakeholder. This resulting shift of focus, in some instances, places the provider in a conflict-of-interest situation. Having posed the moral neutrality of the term managed care, the focus of this paper will be on that use of it which places economics ahead of ethical imperatives inherent in treatment situations.

One purpose of a managed care approach is keeping treatment costs down. Cost reduction is potentially beneficial to each individual patient and the group or the plan membership. These benefits include appropriate, quality care for the individual and resulting cost-savings, which will provide additional benefits for a larger group of people (the entire plan membership).

These relatively recent and dramatic changes in health care delivery in response to economic pressure have contributed to major changes in the relationship between the health care provider and the patient. The professional obligation has been focused traditionally on the individual patient and his or her welfare or particular interests. The physician-patient relationship has expanded to include a wide variety of technicians, specialty health care providers, administrators, and payers who comprise collectively "the plan." Many of those who represent the plan are not directly part of the physician-patient relationship. Payers are assuming a larger role in the management and actual delivery of health care[2] and have become part of the decision-making process that affects the care patients receive. Many of these players act without having any technical or medical knowledge and without knowing either the patient or the provider. To the extent that these other factors represent an expanded universe within which health care is delivered and for which we accept the notion of finite resources, the necessity to balance competing interests is not *per se* reprehensible or extraordinary.

This conservation in the allocation of resources, however, requires the imposition of limits and inevitably leads to conflict. The resolution of these conflicts requires consideration of the interests of all who are stakeholders. Balancing these competing interests rationally and fairly of necessity involves ethical considerations.

Under pressure to keep costs down, managed care plans use a variety of techniques, including pre-authorization requirements, utilization review, and financial incentive payments to limit the services that are provided to patients. The new reality is that physicians are under economic pressure to include consideration of cost in making treatment decisions.

Some health plans and institutions have introduced cost containment financial incentives for providers and some have incorporated contractual restrictions on providers with respect to the information that may be provided to the patient. (The word providers will be used to include not only physicians, but all other professional personnel who are involved, and who will be involved, in the delivery of patient care.) These specific restrictions may be incorporated into a physician contract with a Health Maintenance Organization (HMO) or health care plan and are referred to as "gag rules" or clauses. Some health plans that do not have written "gag rules" have unwritten policies that have been orally communicated.[3] Many providers have become concerned about these restrictions, which are used to inhibit physicians from full explanation of particular treatment options and from saying whether or not the plan covers these treatments. Clinicians believe that these "gag rules" are unethical.

It is not known how many managed care contracts contain "gag rule" clauses. However, some of the nation's largest health insurance companies, such as Aetna, CIGNA, and ChoiceCare, have included statements in their contracts with physicians that seek to limit discussion of treatment options with patients.[4]

Some representative clauses from managed care plan contracts with providers state:

"Do NOT discuss proposed treatment with … (health plan) members prior to receiving authorization. Do NOT discuss the (utilization oversight) process with members. Do NOT give out (plan's oversight) phone number to members."

"Physician agrees not to disparage plan or its processes, programs or policies to any persons, including members or other participating providers."

"Any dissatisfaction with the specialist program should be communicated directly to plan rather than patients or other physicians. Specialist physician who engages in a pattern of derogatory remarks to patients or otherwise damages plan's business reputation may be suspended or terminated."

Under pressure from the medical community, the large managed care organization U.S. Healthcare recently changed its policy to encourage open discussion between physicians and patients about treatment options.[5]

The managed care industry argues that "gag clauses" are intended to prevent medical practitioners from disclosing proprietary information and from criticizing their plans. Nevertheless, considerable anecdotal evidence suggests that some managed care plans have been using "gag rules" to prevent physicians from telling patients about alternative and often more expensive treatments that the plan does not cover or would not like to provide because of their extra costs.

While VHA does not, and likely will never, tolerate an explicit "gag rule," the potential for unwritten, implicit "gag rules" in individual VHA medical facilities exists (see case scenarios in Appendix A). In fact, VHA operates in a climate very similar to the environment that brought about "gag rules" in some private sector health care organizations. VHA is under increasing pressure to compete with other health care delivery systems, to operate under a tight budget, and to deliver cost-effective care. The fact that health care organizations have imposed "gag rules" on clinicians, and that state and Federal governments and regulatory bodies are moving to eliminate the practice should serve as a red flag for VHA.

Developing Societal Consensus

"Gag rules" in effect at many new HMO-style health care plans are not the first examples of censorship over physicians' ability to prescribe or discuss medically appropriate treatment options for their patients. In 1988, the Department of Health and Human Services issued regulations barring all discussion of abortion in federally funded family planning clinics. The regulations were challenged in the case of *Rust v. Sullivan*, argued before the U.S. Supreme Court. Opponents alleged that the regulations would force practitioners in the federally-funded family planning clinics to violate their professional ethics and the law of informed consent, which obligates physicians to render care in a manner respecting of the patient's right to make an informed decision. They argued that the physician plays a central role in a patient's decision-making process by providing the patient with crucial medical facts relevant to medical decisions. They also argued that the rules would prevent the practitioners from exercising their best medical judgment and would expose them to liability for malpractice.[6]

The Court upheld the regulations in a 5-4 vote, ruling that when government pays for a service it can dictate what is said in the course of that service. In the majority opinion, Chief Justice Rehnquist implied that the patient should assume that her doctor might withhold information relevant to her medical condition.

In his dissenting opinion, Justice Blackmun expressed a different view of the doctor-patient relationship. He wrote that the patient "has every reason to expect, as do we all, that her physician will not withhold relevant information regarding the very purpose of her visit." President Clinton rescinded the regulations in 1992.

Since *Rust v. Sullivan*, "gag rules" have become more prevalent in the health care landscape, as cost containment under managed care has emerged to become the predominant health care delivery principle. As these restrictions proliferate, consumers, providers, and policymakers have begun to believe that some cost-cutting measures designed to limit how a physician might prescribe, refer, or otherwise provide

treatment for a patient have been taken too far. Private organizations and consumer advocates have mobilized to push both state and Federal legislative and regulatory measures to protect consumers in the managed care environment. Among those measures are prohibitions on clauses in provider contracts that restrict communication between clinicians and patients. In addition, numerous legislative initiatives seek to limit incentive payments to physicians.

State Legislation

States only recently began to address the issue of "gag clauses" in managed care contracts. Nevertheless, since 1995, 17 states[7] have enacted some form of anti-"gag rule" legislation and many other states have attempted to address the issue.[8] State anti-"gag clause" provisions outlaw managed care contracts that limit in any way or penalize providers for disclosing to patients information about the medical conditions or treatment options, for advocating on behalf of patients, and/or for providing information about HMO policies, including financial incentives or arrangements. Examples of state anti-"gag rule" legislative provisions appear in Appendix B.

Federal Legislation/Regulatory Action/Private Sector Initiatives

Several Federal anti-"gag rule" measures were introduced in the 104th Congress,[9] including the Patient Right to Know Act (HR 2976), which was approved June 27, 1996, by the House Commerce Subcommittee on Health and the Environment.

On November 25, 1996, the Health Care Financing Administration (HCFA) issued a letter to all HMOs that serve Medicare patients informing them that enrollees are entitled to "advice and counsel from their physician on medically necessary treatment options that may be appropriate for their condition or disease." The agency further stated that physicians may not be limited by the HMO in counseling or advising patients. On March 27, 1996, HCFA also published rules restricting inappropriate financial incentives that plans contracting with Medicare and Medicaid often impose on their providers.

Many private organizations recently have adopted policy positions against "gag rules" in managed care plans. Such organizations include: The National Committee for Quality Assurance (NCQA), The American Medical Association's Council on Ethical and Judicial Affairs, American Academy of Family Physicians, The National Association of Insurance Commissioners (NAIC), and the Institute of Medicine. (Additional details appear in Appendix B.)

Ethical Issues

Medical ethics in the United States is often introduced by raising four basic ethical principles:

1. **Autonomy**: the right of the patient with decision-making capacity to control his or her own life by making decisions, according to personal values, being one's own person without constraints either by the actions of another or by physical or psychological limitations.
2. **Beneficence**: doing "good" for the patient; keeping the patient's welfare and best interests foremost.
3. **Nonmaleficence**: avoiding evil or harm to the patient; preventing evil or harm; removing sources of evil or harm.
4. **Justice**: treating all patients fairly and equitably; fair and equitable access to care; burdens and benefits to be distributed fairly; fair allocation of scarce and limited resources.

Included within these four are **veracity** (truth-telling), which implies a full and complete disclosure of all relevant facts and deems it "better" for the patient to know than not to know. Also included are **promise-keeping** and **confidentiality**. All of these concepts recognize and support the unique worth and dignity of the individual and the respect due each patient as an individual.

Fidelity, as contemplated in the physician-patient relationship, is defined as the patient's right to expect continuing service aimed toward the advancement of his or her own interests and the rejection by the

physician of possible conflicting interests. The requirement of fidelity is based on the patient's vulnerability, both physical and psychological, due to illness, impairment, ignorance, and an imbalance of power in the physician-patient relationship. The physician acts as a fiduciary, blunting his or her own self-interest in favor of responsibility for those patients in his or her charge.

The concept of **professional integrity** extends to all providers who are involved with care of patients. All have professional responsibilities, and should make personal commitments, to fulfill the above-noted patient-centered virtues and values.

Often associated with all of these concepts is **advocacy**, or acting in the patient's best interests: pleading; interceding; or speaking for, or in behalf of, the patient.

With the growth of managed care, the emphasis in health care delivery has expanded beyond the individual patient and his or her best interests to inclusion of the group of patients and economic issues of access. Physicians in this setting recognize and account for additional responsibilities beyond those to their own patients, as discussed above. Physicians must be aware of the importance of proper resource utilization in the care of their own patients, while still recognizing responsibility to all other patients who may have equal need and/or claim to the resources in question. This balancing is called stewardship. The ethical principle of justice demands as much.

"Gag clauses" and "disparagement clauses" (to prohibit critical comments about the institution or health care plan) imposed upon physicians, other providers, and employees raise troubling questions about the level of candor or completeness encouraged or tolerated in dealing with patients.

Any employed physician may have additional duties and responsibilities to the "managed care" institution:

a. Observing the institution's bottom line, since it cannot continue operation if there is significant fiscal irresponsibility and the

institution's resources are not husbanded carefully;

b. Containing costs;

c. Participating thoughtfully in technology assessment, resource utilization, outcome evaluation, and good faith peer review.

VHA's Institutional Responsibility to Its Patients

VHA has institutional ethical responsibilities to its beneficiaries: obligations of justice—fair and equitable distribution of scarce and/or limited resources—as well as veracity, beneficence, and fidelity.

Further, the relationship of VHA to its patient beneficiaries is unique, without parallel in modern American medicine. It is based upon the recognition and acknowledgment of a moral responsibility "to care for him who shall have borne the battle, and for his widow and his orphan." Legislation originally establishing the VA was enacted in recognition of this moral claim. Some would argue that this claim is stronger than that which exists between an HMO and its enrollees, where the commitment is based on a contractual relationship in return for premiums paid or as a fringe benefit of employment. The claim will come under review and modification with the new focus on eligibility reform and enrollment.

VHA's Responsibility to Its Physician-Employees

It is well-recognized that institutions have an ethical life of their own.[10] There is an expectation that the responsible organization will not only permit, but actively support, the development of professional ethics and integrity of its employees by such means as providing educational programs and addressing moral and ethical issues that arise in the course of doing business. Such training should encompass those economic issues involved in the appropriate planning of resource allocation and utilization. VHA must be committed to keeping "rationing" decisions and/or economic decision-making out of the dyadic provider-patient situation (or away from the bedside) and addressing such issues at the corporate and institutional level. This relates in a special way to physicians and to patients/enrollees. This

responsibility also encompasses providing physicians and all other professional employees with a well-maintained environment conducive to the delivery of high-quality medical care and with adequate personnel, technological, and fiscal support. It also envisions that those providers will care for their patients in a manner consistent with the ethical dictates of their professions and with the support of the institution in the fulfillment of those ethical dictates. These are obligations of mutual trust and fidelity between patient and physician, between patient and institution, and between physician and institution.

Current Pressures in VHA

The question posed is whether the management methods designed to streamline and improve the delivery of care in VHA will, in practice, impose additional or new ethical burdens and restraints on the ability of individual practitioners to discuss appropriate treatment options with patients. Unknown also are the effects of budget pressures and the drive to "bottom-line medicine" (such as contracting out or eliminating expensive outlier care) upon the relationship between the provider and the patient. Yet to be determined is whether explicit or implicit pressures, or other subtle inducements, will be placed on VHA clinicians to restrain discussing limitations or options of care based on cost considerations or performance incentives, or otherwise to refrain from advocating for their patients.

Some specific developments that parallel initiatives in the community, posing potential opportunities for risk within VHA, are the proposed physician pay incentives and the performance agreements negotiated contractually with VISN directors and at other organizational levels. Although nothing in these formal agreements currently appears to restrict full disclosure to veterans, the conditions exist for such to occur. As VHA evolves in this managed care environment, managers must be cognizant of the potential inherent risks. They must keep ethical issues in the forefront of the thinking process to assure that "Putting Budgets First" does not supplant the ethical and moral obligation of "Putting Veterans First."

VHA practitioners will come under increasing pressure to provide services to more veterans at lower cost during a time of shrinking resources. Realizing this fact, it is also clear that VHA will not always be able to provide all services available in the complete medical repertoire in the health care marketplace to all veterans presenting themselves for treatment. However, honesty and forthrightness in the physician-patient relationship as well as informed consent common law require that providers inform patients of those treatment options that are medically appropriate to their condition and which courses of treatment are available through VHA. They must also be exquisitely clear and straightforward as to what options are not provided by VHA and why, but could be sought by the patient elsewhere or obtained in a more timely manner from another source.

Such ethical considerations are not new to most physicians working in modern American medicine, including VHA practitioners. In the future, their impact on the physician-patient relationship will become increasingly complex. VHA must directly address these ethical challenges as they occur in order to maintain fidelity in its relationships with its patients, its managers, and the veteran community at large.

Recourses Available to Health Care Professionals

There are both formal and informal recourses available to VHA health care providers who feel unduly restrained from providing complete and comprehensive information to patients about their health care choices due to organizational policy or administrative decisions. Currently, physician pay is not contingent on meeting certain budget or productivity goals. However, it is possible in this environment for an individual provider, whose cost profile shows unique variations, to come under pressure to alter practice patterns based primarily on cost considerations.

Formal recourses available to health care professionals who feel constrained or ethically challenged include the following:

a. Internal quality assurance monitors could be designed to document outcome and discussion of treatment alternatives with patients.

b. Presentation of ethical concerns resulting from "gag rules" may be made at clinical practice committee meetings.

c. Consults may be requested of legal counsel and resolved locally or forwarded to general counsel for analysis and opinion. Consultation with Headquarters regarding a discrepancy between local policy or practice and official VHA policy should also occur.

d. The Office of the VHA Medical Inspector is available for consultation by the practitioner who feels that local avenues have been exhausted and needs another level of consultation still within VHA.

e. Physicians can call the Inspector General Hotline if they feel that all other avenues have been exhausted and that implicit or explicit "gag rules" prevent an appropriate informed consent discussion with patients about treatment alternatives.

f. Should an adverse action be taken against a physician, appellate processes are available. The physician's appeal would be reviewed either by a Board of Peers, if the action was determined to be one of professional competence or conduct, or through the regular grievance process if the action was determined to be of an administrative nature. This latter procedure would be adjudicated by a hearing officer who in all probability would be a peer, although a peer is not a requirement. Human Resources Management Service in the medical facility would facilitate the hearing arrangements.

g. Federal "whistle blowing" legislation might be invoked to protect a local care giver if one were to experience reprisal as a result of speaking out about "gag rule" use to restrict information regarding treatment for veterans.

Conclusions and Recommendations

Anything less than open, honest, and forthright discussion with patients regarding their treatment options is unethical and unacceptable. A distinction must be made between *discussion/disclosure* of treatment options in the medical repertoire and *availability*

of any given option within the VHA system. The issue here is that both options and availability must be freely discussed with patients. These discussions should include information about budgetary issues and issues related to justice as appropriate. No provider should be compromised in any way by a management or supervisory influence or direction that would force him or her to violate the informed consent requirements for disclosure and for full discussion of treatment options. There must be no subtle implicit or explicit attempts to impose a "gag rule" on professional staff within VHA. Nor should individual providers allow their loyalty to the system or corporate VHA or intimidation by subtle pressures from colleagues or from supervisors influence or restrict their freedom to speak openly and honestly with patients about their treatment options.

The Under Secretary for Health should formally communicate the position that VHA will not tolerate formal or informal "gag rules," and initiate ongoing procedures to inform administrators, health care providers, consumers, and stakeholders in the veteran community that anything but a free, open, and complete exchange of medical information between patients and health care practitioners will not be tolerated.

Some specific actions might include, but not necessarily be limited to: a) an Information Letter (IL) to raise the level of awareness regarding the Informed Consent regulations and policy that require that patients be informed of all reasonable treatment alternatives, including a clear statement that no "gag rules" will be tolerated in the VHA; b) QA monitors and/or questions on the patient-satisfaction survey designed to address the issue of full disclosure and free discussion of treatment alternatives with patients; and c) emphasis on open and honest disclosure and discussion of physician pay incentives, where those incentives are tied to allocation of resources or cost containment actions.

Appendix A: Hypothetical Scenarios

While these cases may appear to be stating the obvious to many health care providers, they are real examples that have been sanitized. These examples were selected to show how compliance with an unspoken part of the organizational culture can evolve, even when it is not highlighted as a "gag rule" *per se*.

1. Veteran X, a veteran of the Airborne troops during the Korean War, was 80% service-connected for bilateral hip injuries. In 1991, he had a left hip replacement followed by 21 days of daily inpatient rehabilitation and 2.5 months of outpatient rehabilitation treatment, three times a week at the ABC VA hospital. He did well until 1995, when the right hip began to cause increasing pain and lack of mobility. He returned to the ABC VA hospital and sought similar surgical and rehabilitation treatment for the new problem.

   In the meantime, because of budget limitations, the Rehabilitation Medicine Service at the ABC VA hospital had been forced to down-size its physical therapy technician staff from nine to four. As a result, patient rehabilitation treatments have been severely limited.

   The veteran was readmitted and underwent right hip replacement on August 14, 1996. Inpatient rehabilitation was provided twice weekly for two weeks, at which time he was discharged. Outpatient rehabilitation was scheduled for 10 visits, two each week for five weeks. The physiotherapy staff had previously been advised not to discuss the difference in rehabilitation schedules with any "new patients."

2. The STU VA Clinic was a free-standing rural facility. It had an active cardiac clinic, with a staff of four EKG technicians. Because of budgetary limitations, the EKG tech staff was cut to one, Linda Hoskins. Three weeks after the cut, Ms. Hoskins was injured in an auto accident in which both her legs were broken. No EKG tech staff are now available. The physicians and nurses in the cardiac clinic have been instructed not to discuss the lack of availability of EKGs with patients, families, or other clinic employees.

3. A high level manager in Network 65 knows that he is being considered for a sizable year-end bonus. To make his administration "look good," he suggested to all facility directors in his service area to "keep everything on an even keel," minimize appeals for expensive drugs, avoid requests for transplant surgery, etc. Dr. H, a nephrologist at XYZ VA facility, submitted a request for a kidney transplant for one of his End Stage Renal Disease (ESRD) patients. His request was denied, and he was reminded of the limitation of funds that might require some reduction of employees or possible program cut backs that could affect his service.
4. A physician in the outpatient clinic recommends a specialty consult to the patient. This particular specialty has a 4-month waiting time for an appointment. Although the physician knows that the patient could be seen in the community within approximately a week, he does not inform the patient that a prompt appointment within a week would be possible if the patient is willing to see a private physician and use his Medicare benefits and/or pay privately. The full range of options is not disclosed to the patient, thereby preventing a fully informed choice and prompt treatment for a potentially serious problem.

In each of these cases, the full range of treatment options was not clearly explained to the patient, and staff ability to act or respond to patient need was compromised by an apparent pressure to withhold information.

Appendix B: Notes on Developing Societal Consensus

State Initiatives

Examples of state anti-"gag-rule" legislative provisions:

A health maintenance organization shall not refuse to contract with or compensate for covered services of an otherwise eligible provider solely because such provider has in good faith communicated with one or more of his current, former or prospective patients regarding the provisions, terms or requirements of the organization's products as they relate to the needs of such provider's patients. (Massachusetts)

No health care provider may be penalized for discussing medically necessary or appropriate care with or on behalf of his or her patient. (Georgia)

The carrier shall not terminate the contract with a provider because the provider expresses disagreement with a carrier's decision to deny or limit benefits to a covered person; or because the provider assists the covered person to seek reconsideration of the carrier's decision; or because a provider discusses with a current, former, or prospective patient any aspect of the patient's medical condition, any proposed treatments or treatment alternative, whether covered by the plan or not, policy provisions of a plan, or a provider's personal recommendation regarding selection of a health plan based on the provider's personal knowledge of the health needs of such patients. (Colorado)

Congressional Initiatives

The Patient Right to Know Act (HR 2976) was approved by House Commerce Subcommittee on Health and the Environment on June 27, 1996. The language contained in the legislation was a scaled-back version of the original bill, which included broad language banning limits placed on physician-patient communications in managed care plan contracts. The new version would only ban plans from writing contract clauses that limit what physicians can say about treatment options. It would allow contract clauses that prohibit providers from criticizing plans or disclosing financial incentives and how decisions to authorize or deny care are made. Provisions limiting action plans can take against providers also were stripped from the bill.

In the final days of the 104th Congress, "gag rule" legislation (S 20005) was proposed as an amendment to the Treasury Department–U.S. Post Office spending bill; the amendment failed. In February 1997, President Clinton declared his support for anti-"gag rule" legislation.

Federal Regulatory Initiatives

Not only have the Federal and state legislatures begun to take action to protect consumers, Federal regulators have recently taken steps to address the issue. Recognizing the pressure financial incentives can place on physicians to limit or deny care, on March 27, 1996, the Health Care Financing Administration (HCFA) issued regulations governing financial incentives that managed care plans serving Medicare and Medicaid often impose on their providers. These regulations became effective January 1, 1997.[11]

The rules will require health plans with Medicare and Medicaid contracts to disclose the nature of physician incentive plans to HCFA or to state Medicaid agencies and to provide a summary of such arrangements to beneficiaries when requested. Information of this nature would help patients determine whether their doctor's interests are concordant with their own. Under the regulations, plans will be prohibited from making specific payment to doctors to limit or reduce necessary medical services. The rules also outline several requirements health plans must comply with to ensure that they do not place undue financial risk upon their physicians.[12]

Private Sector Initiatives:

The National Committee for Quality Assurance (NCQA), the largest accrediting entity for managed care organizations in the United States, recognized the importance of ethics by adopting a standard related to members' rights and related grievance procedures. Recently, NCQA issued a clarification of its standard for Members' Rights and Responsibilities, which states that "at a minimum, the organization has a written policy that recognizes the following rights of members to participate in decision making regarding their health care and prohibits restrictions on the clinical dialogue between practitioner and patient."[13]

In January 1996, the American Medical Association's Council on Ethical and Judicial Affairs released the following statement on "gag clauses:"

The physician's obligation to disclose treatment alternatives to patients is not altered by any limitations in the coverage provided by the patient's managed care plan . . . Patients cannot be subject to making decisions with inadequate information. That would be an absolute violation of the informed consent requirements. If these [gag] clauses are carried out and the physicians are subject to sanction, a reduction of patient quality of care will result.[14]

The American Academy of Family Physicians issued the following policy statement on family physicians' interaction with managed care plans:

Physicians must be able to discuss any information, clinical or financial, necessary for their patients to make informed decisions regarding their medical care.[15]

The National Association of Insurance Commissioners (NAIC), an association of insurance regulators from all 50 states, the District of Columbia, and the four U.S. territories, has developed model state laws in the area of managed care. Many states base their laws on NAIC models. The Managed Care Plan Network Adequacy Model Act contains a provision that would prohibit health carriers from preventing providers from discussing treatment options with covered persons without regard for the health carrier's position on the treatment options, or from advocating on behalf of a covered person within the plan's utilization review and grievance processes.[16]

An Institute of Medicine (IOM) report, published in August 1996, stated that managed care plans with gag rules should be barred from participating in Medicare. The IOM-convened committee expressed its concern about potential restrictions on the physician's traditional patient advocacy role and said that it favors the abolition of payment incentives or other practices that may motivate providers to evade their ethical responsibility to provide complete information to their patients about their illness, treatment options and plan coverages.

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11. Relief of Patients' Suffering: An Ethical Overview of a Practical Responsibility

Charge and Scope

The charge to write this report includes addressing the following questions:

A. What should count as suffering?

B. Who should make the determination that a patient is suffering?

C. Are health care providers ethically required to attempt to relieve the sufferings of patients?

D. Are there limits to these obligations?

E. Is there ethical justification for providing relief of suffering that might produce harmful, unintended consequences including loss of life (i.e., double effect reasoning)?

F. What is the institutional responsibility to relieve suffering?

The arguments and conclusions of this report are drawn from lengthy discussions among committee members and a sample of other clinicians, and from reviews of VA policy and relevant literature, particularly Eric Cassell's book, *The Nature of Suffering and the Goals of Medicine*. This report separately addresses each of the specific questions outlined above. We have included three case stories to illustrate examples of suffering as experienced by different veterans and the responses of health care providers. We hope that this report will be a catalyst for future discussion, education, clinical practice, and

policymaking within the VA. We also hope that this report inspires providers to accept relief of suffering as a compelling and central goal in the care of patients.

Discussion

A. What experiences of patients should count as suffering?

Cassell writes that "most generally suffering can be described as the state of severe distress associated with events that threaten the intactness of the person (p. 33)… in everyday life and function . . . compared to the person's or culture's ideal (p. 50)." Cassell identifies suffering as disruptions of personhood, that is, disruptions of a patient's estimation of his or her individual health, identity, interpersonal abilities, and social standing. For the purposes of this report, the committee defines suffering as the subjective perception of physical and personal disruption, caused or exacerbated by disease and illness. This definition is intentionally broad: it captures obvious and obscure aspects of suffering.

Disease and illness can assault patients' wholeness, distort their sense of meaning, affect their relationships and social standings, and seize control of their lives. They can elicit mental aberrations and psychological and spiritual extremes of anger, fear, shame, and despair. Providers must understand that these disturbances can coexist and overlap and manifest themselves in behaviors and conditions including denial, depression, abuse, and violence. Finally, suffering that results from disease and illness can be episodic and/or progressive and/or cumulative.

Suffering has both somatic and nonsomatic dimensions. Physical ailments, as well as non-physical illness, might cause physical suffering. Bodily disturbances are usually felt in physical symptoms, and these are often identified in the course of work-ups by health care providers. The best evidence of the link between non-physical illness and somatic suffering is seen in relief of somatic symptoms with successful treatment of depression, panic, anxiety, or stress.

Non-somatic suffering includes psychological, spiritual, relational, social, functional, and communicative disturbances. Examples of this kind of suffering include a sense of diminished capacity for experiencing love, friendship, and daily functioning. Sick persons might express feeling burdensome, isolated, vulnerable, stigmatized, and endangered. Also, sickness can be more intensely suffered in unsettling contexts such as divorce, unemployment, poverty, and homelessness.

We specifically differentiate between suffering and pain because a failure to do so could impede relief of either. Pain and pain relief have been addressed elsewhere by VA. For the purposes of this report, we regard pain in a literal, perhaps reductionistic sense, as aching or stabbing or burning physical discomfort. Pain can cause suffering and suffering can increase pain. But not all suffering includes pain, and not all pain causes suffering.

B. Who should make the determination that a patient is suffering?

Cassell writes, "Ultimately, to know whether a patient is suffering, you must ask the patient (p. 245); … to know in what ways others are suffering requires an exhaustive understanding of what makes them the individuals they are (p. 212); and, … there is much to be seen that can only be seen by those who care (p. 155)." Health care providers and patients (or surrogates) together should make determinations of suffering. Patients define their own suffering, but they typically define it in response to questions and inferences from providers to whom they report symptoms and worries. Providers can come to know patients' suffering only by asking them about it. Asking is a professional responsibility.

Obstacles for Health Care Providers

There must be a concerted effort by all health care providers who care for patients to ask about suffering, because suffering is easy to overlook and not asking could cause additional suffering. There are obstacles to asking that providers should recognize and try to overcome. Different health care disciplines are trained to pay attention to different aspects of disease and illness. For example, physicians are

trained to treat pathology and associated physical symptoms. Social workers are trained to address patients' psychosocial needs; chaplains attend to individuals' spiritual needs. We acknowledge that these examples take a narrow view of what providers are trained to do, but we include them to make the point that different training could lead an individual provider to overlook a critical component of a patient's suffering simply because asking didn't occur to him or her.

Some health care providers may choose not to ask because it makes them vulnerable to suffering as well. Because of their own fear or avoidance of suffering, they may respond to patients with impatience, disapproval, excessive reasoning, challenging, and labeling. Or, providers may avoid asking about a patient's suffering because they lack the requisite skills or disposition. Asking takes time and time might be limited for either party. Asking can elicit a depth of revelation and relationship to which one or both provider or patient might not want to go. Individual patients might feel fearful, or intruded upon, or invaded in communicating about their suffering, and so disposed to silence. These feelings might be shared by providers as well.

Systemic barriers can sabotage relief of suffering. The skills and practice of relief are not prioritized in providers' professional education and training. Additional barriers include poor communication among providers, fragmentation of care, excessively restricted funding, inefficiently utilized resources, and eligibility criteria that limit access to necessary care.

Suggested Guidelines for Health Care Providers

We offer the following as suggested guidelines that providers should carefully consider and implement:

- First, relief of suffering begins with empathetic and compassionate practitioners who care enough to ask, and who, in asking, elicit trust, rapport, confidence, hope, and cooperation of their patients. In other words, health care providers who attempt to relieve suffering need to take a real interest, establish an inspiring connection, and risk experiencing some of their patients' suffering that seeks relief.

- Second, relief of suffering requires respect for the person. Suffering persons often need an invitation to communicate their feelings, because suffering can involve negative personal matters that the sufferer feels uncomfortable in sharing or at risk in exposing. Respect gets expressed by answering questions and continuing inquiries begun by patients, correcting misunderstandings, and relieving fears. In addition, respect is shown by preserving confidentiality and privacy, and eliciting consent.
- Third, in order to relieve suffering, health care providers need to connect with the whole person, the individual who is embodied, subjective, relational, communicative, and socially and culturally influenced. Providers should attempt to elicit the patient's understanding of disease, illness, and the suffering that arise from them. They should ask about suffering across the range of possible personal disturbances. Possible physical and non-physical suffering should be directly addressed.
- Fourth, health care providers need to nurture the person when they attempt to relieve suffering. This can occur by establishing a reassuring presence with friendly facial expression and relaxed body language. It requires patience and active listening, which may mean being there without necessarily doing anything. This can happen by asking open-ended questions, acknowledging what the person is saying, and accepting his/her reactions.
- Fifth, relief of suffering can very importantly include validating patients' individual feelings and perceptions of suffering as being normal and expected.
- Sixth, health care providers responsible for relief of physical suffering should listen carefully to the patient's account of bodily suffering. This stance requires careful observations, competent examinations, and accurate diagnoses. Physical symptoms need to be treated and evaluated with conscientious follow-up.
- Seventh, relief of personal, relational, and social suffering can occur when health care providers identify factors that seem out of control. This approach might require trial-and-error problem

solving and other strategies, including those suggested by patients. Providers can propose alternative outlooks and outcomes if the suffering has induced rigidity and fatalism. In some situations, the provider may encourage the restoration of impaired relations, invite renewed or expanded communication, and assist the patient in recovering autonomy, a sense of control, a role in a story, a place in the big picture.

- Eighth, in the present system of providing medicine and health care, the primary care provider should initiate and coordinate relief of suffering. Primary care providers need to practice within the parameters of their expertise, abilities, and limits and refer to others (such as social workers) for services that exceed these parameters. It is also very important for health care providers to keep informed of a patient's ongoing experience, such that one can talk meaningfully with the patient and other caregivers about how things are going.
- Ninth, the patient's primary care provider should foster coordinated care among the involved services. Documentation in the patient's medical record should be sufficiently detailed to assure meaningful communication between providers, especially if providers change.

C. Are health care providers ethically required to attempt to relieve the sufferings of patients?

The positive ethical duty to relieve suffering is one that providers accept in choosing and learning their professions. They are generally obliged, upon the consent of patients, to take measures to relieve experiences that patients and they have identified as suffering.

There are several sources of this ethical responsibility. One exists in the virtues of the professions of medicine and health care. In this context, "virtues" are standards of excellence that guide providers in their practices. Providers should exhibit intellectual ability to learn professional virtues, personal inclination to practice them, and prudential wisdom to realize them. Relief of suffering, combined with

professional competency, respect for persons, effective communication, compassion, and mercy are a group of virtues that providers should strive to realize.

Relief of suffering is a traditional professional duty of providers: it is explicitly identified as such in historically influential and currently governing canons of medicine, nursing, allied health, and corporate health care practices. Relief of suffering is also part of health care providers' fiduciary responsibility for patients. Fiduciaries accept professional and legal responsibility for matters such as loyalty, truthtelling, informed consent, and putting patients' interests first. Thus, since fiduciaries are responsible for securing the best interests of their clients, and suffering that is not voluntarily borne detracts from patients' interests, providers are responsible to attempt to relieve that suffering.

Relief of suffering is also required by ethical principles to which providers subscribe, including respect for persons, beneficence, and nonmaleficence. Respect for persons includes attempting to relieve suffering primarily because successful relief restores or assists patient self-determination. Beneficence elicits attempted relief of suffering because successful relief contributes to patients' well-being, for example, enabling patients to better assess their own best interests. Nonmaleficence compels attempting to relieve involuntary suffering caused by disease and illness because such suffering can constitute harm to patients.

D. Are there limits to these obligations?

Limits on this positive ethical duty originate in society, in patients, and in providers themselves. Society's limits stem from specific cultural interpretations of health and medicine, disease and illness, and associated suffering. Our society defines health, disease, illness, and suffering more broadly than it does the responsibilities of health care givers. Our society holds that many factors contribute to understanding health, disease, illness, and suffering. These factors include, but are not limited to, science, technology, medicine, nursing

and allied health, education, age, class, race, gender, genetics, diet, fitness, the environment, psychology, religion, faith, hope, spirituality, and law. Our society obliges health care givers to attempt to relieve sufferings that fall under their competencies, and to refer appropriately either within health care or beyond it for relief that exceeds their responsibilities. Our society does not expect health care providers to redress all causes of diseases and illness and to relieve all human suffering.

Patient-originated limits on the duty to relieve suffering are found in patients' bodies and particular conditions, in patients' knowledge, attitudes, and dispositions, and in their preferences, rights, choices, and actions. The body has a life of its own, and certain advanced physical conditions impose limits on the duty to relieve suffering. Patients primarily determine whether they are suffering or not. A patient's repeated determination that he or she is not suffering, appearances and providers' beliefs to the contrary, usually sets a limit on providers' responsibilities. So does a patient's persistent non-compliance with consensual therapies. So do states of being that patients define as suffering, but for which they do not seek or for which they refuse relief. Examples can include sufferings that the sufferers feel are voluntary, justified, maturing, purging, sacrificial, atoning, mourning, and defeatist. These limitations should not discourage providers from continuing to attend to patients' suffering. This is particularly true for patients in denial or refusing treatment for severe depression.

For individual health care providers, the duty to relieve suffering extends only to patients within their care. Additional limits are encountered in providers' specific education and training, their expertise and competence, their finite knowledge and abilities, their work situations, and their personalities.

E. Is there ethical justification for providing relief of suffering that might produce harmful, unintended consequences including loss of life (i.e., double effect reasoning)?

Many clinical responses to relieving suffering could have

unintended negative consequences. An example is sedating a patient who is anxious and afraid of an imminent surgical procedure, such that one cannot talk with or be comforted by one's family. Another example is treating a patient's advanced dyspnea with drugs that could also hasten the patient's death. Some clinicians argue against aggressive treatment because they fear that this could cause death. Clinicians often voice the same reasoning about aggressive treatment for pain.

The ethical justification for giving helpful treatments that produce harmful consequences follows from the principle of double effect. This principle stems from the common human experience that morally right or good actions sometimes have unintended wrong or bad consequences. In health care these actions are justified if the following five conditions are met:

1. the intervention is indicated and appropriate,
2. informed patients or surrogates consent to risking the side effects,
3. the negative side effects are truly consequences of the intervention, not means of achieving it,
4. providers do not intend or directly cause the negative side effects, and
5. the benefits of the intervention outweigh the harms of the side effects.

Double Effect Reasoning and Pain Control: Objections and Replies

In spite of this ethical justification, undertreatment of acute and end-of-life pain continues, due to some health care providers' objections to the addictive and/or depressant effects of narcotics. This reservation is influenced by the traditional professional rule against fostering dependency, and the perceived ethical and professional prohibitions and legal risks of causing death by overdosing. Indeed, several objections have been raised to the principle of double effect, however, they are not sufficiently convincing to undermine its guiding value.

For example, some individuals object to double effect reasoning

because they consider it to be a religious principle rooted in Roman Catholicism and not appropriate for a pluralistic secular society. We hold that double effect reasoning is primarily rational, not religious. The reasoning is embraced beyond Roman Catholicism, and it is an ethical staple of hospice.

Another objection is that pain control often directly, not indirectly, causes death. After reviewing the literature on pain management and discussing this with clinical experts, we believe that the multiple effects of available pain medications are much misunderstood. Although clinicians often worry that pain medications may cause death, this is rarely the case. A third objection to double effect reasoning is that it focuses too exclusively on the intentions of the involved parties. As intentions are impossible to verify, considerable causing of death, disguised as pain control, could occur. This objection is really one to an abuse of double effect reasoning. We hold that possible abuse does not undermine the value of double effect reasoning. It does, however, raise a concern about deception, but deception is morally another matter that stands apart from the principle *per se*.

Some individuals object to double effect reasoning because they view it as being too restrictive in its consideration of consequences of beneficial therapies. For example, one can hold that the beneficial consequence of adequate pain control justifies other outcomes (e.g., death) regardless of the intentions of the involved parties and the causal efficacy of the utilized substances or methods (i.e., even if the providers intend death, and even if the substances or methods cause death). This objection merely suggests that double effect reasoning is unnecessary. Thus, we do not believe that a rebuttal is necessary.

A fifth objection is that directly causing the deaths of patients is not always wrong. Double-effect reasoning is again, albeit differently, unnecessary in justifying pain control that also effects death.

Lastly, some individuals object to double effect reasoning because they consider the law as being intolerant of this justification for unintentionally causing death. This view holds that foreseen consequences of medical acts are likely to be held as both caused and

intended. Several states' laws (e.g., Ohio, Minnesota), however, explicitly adopt double effect reasoning in permitting adequate pain control for dying patients while still prohibiting killing or causing death. In addition, all prior case law supports the non-culpability of unintentionally causing death while trying to treat pain and alleviate suffering.

Treatment of Pain

We recognize that challenges exist to the recommendation that health care providers alleviate or minimize the suffering associated with pain. Failure to ask about pain is the initial challenge. Not asking sends a signal to some patients that it is best not to report or to understate their pain. Some providers' unfamiliarity with opioids, analgesics, and other modalities of pain control exacerbate the problem. Medical and nursing students are not sufficiently schooled in pain's physiology and control. Unacknowledged attitudes that pain must be borne present another challenge. Especially noteworthy is the lack of institutional (facility) policy and protocol requiring effective diagnosis and relief of pain-driven suffering. The harmful consequence implicit in all these observations is that providers routinely do not relieve suffering from pain that they could relieve.

We adhere to the principle that inadequate pain control is bad for patients. Poor pain control might reinforce the belief that pain necessarily accompanies dying. Acute pain can be so debilitating that it sabotages patients' attempts to seek relief from other kinds of suffering. Chronic pain may cause patients to consider suicide.

Treatment of chronic pain is often more complicated than that of acute pain or pain experienced while dying. Attention to pain-related behavior and suffering is often minimized in patient-provider discussions. In the treatment of chronic pain, providers and patients need to develop a plan of care that allows the patient to function as normally as possible. In some situations, providers need to share both uncertainty and authority with patients by clarifying that further medication interventions are probably futile for eliminating the pain.

We urge providers to alleviate or minimize the suffering associated with acute pain, end-of-life pain, and behavior and suffering associated with chronic pain. Any patient (and especially dying patients) suffering from acute pain should be offered pain control. Pain control consists of an informed, coordinated, consensual, documented, and revisited regimen of medication and other therapeutic interventions that eliminate or reduce the pain. Providers should encourage patients to report pain and inform them that acute pain need not be borne. Providers should administer sufficient pain control to relieve it. The measure of success is the patient's report that he or she is no longer suffering from pain.

F. What is the institutional responsibility to relieve suffering?

We suggest the institutional responsibility to relieve suffering lies in four domains:

1. Patient care should be scheduled and coordinated to allow more time for health care providers to elicit patients' perceptions of suffering;
2. Educational programs should be designed and implemented to ensure that providers are adequately skilled to address patients' suffering;
3. Research should be conducted to better understand what contributes to suffering and to evaluate interventions designed to relieve it; and
4. VHA should advocate changes in eligibility, access, and scope of services that contribute to more effective relief of suffering of sick veterans. We elaborate on these responsibilities below.

Schedule Adequate Time and Coordinate Patient Care

Institutions can facilitate opportunities for clinicians to ask about patients' suffering by scheduling more time for listening during outpatient visits, and restructuring traditional care teams so that interdisciplinary communication is maximized. Special consultative

clinical teams promoting the use of palliative care could be staffed. These special teams might include a psychologist, social worker, nurse, chaplain, and physician with expertise in palliative care. Any of these individuals could serve as the facility's palliative care case manager. Palliative care is widely understood as pain control and other comfort measures extended to dying patients. VHA's hospice consultative teams have expertise in palliative care and are currently available to assist with or provide end-of-life care. We advocate expanding the meaning of palliative care and the role of palliative care teams or case managers to include special interventions that would attempt to relieve any patient's suffering when routine measures fail.

Education

Because suffering does not fit within one discipline, educational programs need to be developed for students, trainees, and experienced clinicians in many of the clinical disciplines, including social work, nursing, medicine, psychology, chaplaincy, and other health care professions. Providers should learn the most recent recommendations of drugs, dosage, administration, and frequency for pain management. Educational programs should be case-based, clinically relevant to the learner, and interactive. Particular attention should be focused on the importance of listening to patients, asking them open-ended questions, and fostering trust in the relationship. In other formats, educational programs will need to foster sufficient self-awareness on the part of clinical trainees and clinicians to ensure that they do not impose their own projections and interpretations on the experiences that the patients report. In clinical settings, role modeling can help clinical trainees develop favorable attitudes about exploring suffering and learn practical skills such as talking to patients, listening to their stories, respecting their experiences, and knowing when to recognize the need for outside resources to help in the relief of the patients suffering. Educational objectives that promote desirable attitudes and skills are as important as those that target points of knowledge.

Research

Research needs to follow several paths to advance knowledge in this area. First, it should be patient-centered and characterize the nuances of suffering such as how it feels, and what makes it better or worse, and how the patients respond to the clinicians' attempts at trying to relate to and relieve it. Research studies should also characterize secondary suffering on the part of family members and care providers. Second, research needs to identify the most efficacious strategies for eliciting and relieving suffering. This research will also need to identify those strategies that might work as part of institutional programs. Third, research needs to evaluate the effectiveness of educational interventions. Finally, research should evaluate quality improvement mechanisms to ensure that standards of practice with regard to relief of suffering are maintained and improved over time.

Eligibility, Access, and Scope of Service

VHA and each individual facility need to consider how policy decisions about the delivery and scope of health care effect the health, well-being, and suffering of veterans. Reduction of suffering related to disease and illness should be a desired outcome of comprehensive service and quality of care. Performance measures such as those developed for hospice care should be developed and employed to monitor this dimension of care.

Stories of Suffering

The Story of John: Suffering from Pain

John, a 66 year-old Korean War veteran, was admitted with excruciating pain in his right hip. He had suffered the pain for seven days and was unable to walk. For the past three months his private physician had prescribed 50 mg of Demerol prn and that plan had achieved very little relief. His wife, Marilyn, was at his bedside. John's facial expression suggested pain and fear. Marilyn was anxious. Both John and Marilyn looked fatigued and appeared depressed.

History and physical examination revealed that John had been diagnosed with prostate cancer several years ago. There was clinical evidence of severe bony pain over the upper lateral aspect of his right femur. No other sites of bone pain could be elicited. Aggressive pain control was immediately instituted with nonsteroidal anti-inflammatory drugs (NSAIDs), oral morphine, and a night time sedative. Later that day on evening rounds, John's pain had reduced from 10 of 10 to 4 of 10 on the visual analogue pain scale. He was much more relaxed. Marilyn, asleep in the bedside chair, awakened easily and expressed her thanks for the almost miraculous relief of John's pain. The next morning John said he had his first good night's rest in several weeks. His pain was well-controlled except on movement. He consented to additional diagnostic studies and received an extra dose of morphine. A bone scan revealed a single metastatic area in his right femur. After consultation with the radiotherapist, John agreed to a single hypo-fractionated dose of radiotherapy to his femur. He was discharged to home two days later on oral medications. He was assisted in entering his community's hospice program after a full discussion with him and his wife about his prognosis. Two weeks later John was able to walk and enjoy outings with his grandson. He died seven months later at home with support from the local community hospice.

John: What to Ask About

John's suffering is primarily physical. He is additionally suffering relationally and socially because of the physical suffering. What should

providers ask in attempting to relieve John's suffering?

The lack of pain control at home is the primary source of the current suffering. In the story, adequate pain control reduces the suffering. The VAMC pain regimen is informed, effective, and appropriate. Why was it not provided at home? Did John not report his pain? Did he understate it? Was he fearful that the pain meant spread of his original cancer? Were John and his family too accepting of pain-based suffering? Did they not know that they could ask for pain control? Were they not informed about pain control? Did they think they should not ask (e.g., they believed they should keep a stiff upper lip, or, they were too intimidated to ask)?

Did the home town physician not hear John's pain? Not observe or infer its effects in his life? Not know how to redress it (i.e., pharmaceutical ignorance)? Not want to address it (e.g., John is a whiner, or pain is inevitable, or pain is good for the soul, or John will not become a bothersome addict while under my care)? Did the physician fear addressing it (e.g., prescribing opiates and analgesics invites trouble)? Or, simply, did the physician not ask about pain?

The story's descriptions of the characters give hints about what else to ask. John's physical suffering is also non-physical because effective relief began not with simply observance of symptoms, but with him telling his story to the VAMC physicians. Those physicians initiated relief of suffering by eliciting a complete medical, family, and social history. Also, John's suffering disturbed many aspects of his personhood. His body and bodily functions, mobility, overall functioning, sleep, feelings, spirit, and life plan are disrupted. Additionally, John's suffering was relational and contagious. His wife and grandson (and probably others back home) had caught it. Each person had come to suffer uniquely. Their sufferings combined to strongly disturb the quality of family life. Family disruption was next in the downward spiral. The family's psychological and spiritual suffering manifested in their fear, frustration, isolation, maladjustment, powerlessness, sorrow, and dread that they brought to the VAMC. Finally, the suffering in this story was acute, progressive, and

overwhelming. John and his family sought reassurance that they would survive these sufferings. The VAMC staff provided that reassurance, in large part by effectively communicating about the causes of the suffering and addressing them.

The Story of Paul: Suffering from Morbidity of Treatment

Paul, a 54 year-old veteran, was evaluated for liver transplant at the local VAMC and admitted to a VHA transplant center for more comprehensive evaluation. The patient and referring hospital staff had been hopeful that he would be accepted for transplant. Paul had been an alcoholic, but had stopped drinking many years before. He received consistent support from the VA Ambulatory Care Clinic's substance abuse team in sustaining sobriety during the wait for transplant.

After several weeks of evaluation at the transplant center, Paul was denied the liver transplant. At that time he was offered treatment for cancer that had been discovered during the transplant evaluation workup. The determination of the specific oncology protocol would be communicated following discharge. Paul was discharged to the referring VAMC to receive outpatient dental work prior to chemotherapy. He had to travel 200 miles round trip several times for the dental work. He suffered excruciating pain and loss of teeth. Morphine made him ill. During this time, communication about the oncology protocol proved futile. Repeated requests from the tertiary VAMC were answered by "doctors are still considering the options."

Paul was generally depressed, fearful, anxious, and lonely. Contributing factors were disease and disabilities, rejection for treatment, system inefficiency, family abandonment, marginalization, and impending death. Abandonment and rejection were shaping themes of Paul's life. A parent had abandoned him when he was a child. His wife had divorced him and left him with two children to raise. He had adapted in part by drinking excessively. Family violence, alienation, and loss followed.

At the time of admission to the local VAMC, family relations were strained. Some family said "he brought it on himself," and most of the

family denied his plight or displayed minimal concern. He was greatly afraid that the family would further abandon him. Paul was also newly disturbed by the tertiary center's delay in prescribing his cancer therapy and the burdensome travel for dental treatment. He had felt a surge of desperate urgency about his liver transplant, and the health care system had responded slowly, indifferently, and bureaucratically. Paul had lost faith in VHA.

Health care providers from the local VA hospital and outpatient clinic finally came to grips with Paul's estrangement and suffering. His social worker and addiction therapist helped him overcome his resistance to talking with family members about his feelings regarding illness and prognosis. A brother-in-law was the first to grasp the seriousness of the situation, and he rallied other family. Paul's elderly mother came from another state and provided the 200-mile round trip transport for dental treatments. Two brothers, two sisters, a son, and a daughter communicated among themselves about their concerns, then pulled together to be with Paul in this critical time in his life. Everyone's quality of life improved.

Paul: What to Ask About

Paul's physical sufferings include bodily disabilities, discomforts and pain stemming from liver disease, cancer, dental extractions, and opioid therapy. A primary source of suffering was the combined failure of Paul's local and tertiary caregivers to organize and implement a plan of care that would provide comprehensive relief of these somatic morbidities. Why did the tertiary caregivers respond inconclusively for several weeks regarding an oncology protocol that they themselves had promised the patient? Why did local caregivers tolerate the delay? Why did morphine make Paul ill? What non-opioid pain control did the local health care providers offer for his pervasive pain?

This story alerts us about other sources of Paul's suffering. Paul's social worker, addiction therapist, and primary care physician from the local VA made a good start on relieving his suffering by asking about his social and family histories. Paul's relational and social sufferings were

acute, chronic, progressive, and cumulative. His life plan and his overall sense of meaning had dwindled. Alcoholism had severely strained family relations. Loss of family, indeed active rejection and negligence by the family, were hastening his death. Isolation, maladjustment, powerlessness, sorrow, and awareness of death built up. Yet, Paul was sufficiently hopeful about life and health that he sought life-sustaining and palliative medical treatments for his terminal and chronic conditions. VHA's slow response to meet Paul's needs triggered an old feeling of abandonment and a new one of despair.

Most of the relief of Paul's suffering came from his family. Family members forgave old offenses. They attended to Paul's spectrum of needs. The family convened and assured Paul that he would survive his immediate dire circumstances. Paul's family could not eliminate all suffering secondary to his lethal diseases. But they would soften suffering's final sting in their solidarity with Paul in his dying.

The Story of Michelle: Suffering from Mental Illness

Michelle, a 35 year-old single woman, had been in therapy with a dozen different therapists over many years. Michelle was brought to the local VAMC for treatment by a friend who had observed persistent suicidal thoughts and uncontrolled self-abusive behavior. Michelle was living in a tent in a public park. She was regularly abusing alcohol and prescription drugs. Her history included setting fires and cutting her forearms with a razor blade. The cuts were many and deep. She kept them hidden with bandages and long sleeves, even in the summer. The concerned friend had brought her to receive treatment and relief.

Michelle was estranged from her family. As a child, she had been sexually abused by brothers and neighbors. The family had neither believed nor prevented the abuse, effectively turning a blind eye to the situation. The family remained in denial that anything was wrong, despite Michelle's aberrant and self-destructive behavior. They professed embarrassment and would not visit Michelle. In their small town, their shared guilt would bring down the house should things be exposed. In addition, Michelle was torn by society's conflicted ideals.

On the one hand, she was a bright and intellectual individual who had amassed many college credits without completing a course of study. Also, she served competently and honorably in the military for four years. On the other hand, she was morbidly obese. She was shunned and ridiculed because of her size. This rejection and ridicule caused her great discomfort and deflated any esteem she might have gained because she was smart, schooled, and a veteran.

Michelle was hospitalized at the local VA. The treatment plan was to address the life-threatening, self-destructive behavior, followed by outpatient therapy. In this hospitalization, a team of three individuals combined to relieve an element of Michelle's suffering. The team included an out-patient psychologist, an in-patient psychiatrist, and a social worker. A first breakthrough occurred in an in-patient group therapy session with the social worker. Michelle said that for the first time in her life, as best she could remember, she felt that she wanted to die. It was her first reported perceived feeling of the admission. Albeit depressed and wanting to die, she was happy that she was having a real feeling. Lasting only a few minutes, it was the beginning of something real. It seemed like a light at the end of the tunnel.

Unfortunately, other caregivers at the local VA added to Michelle's suffering. Some ward staff believed that self-abusive behavior was attention-seeking and manipulative. They actively alienated Michelle by treating her as if she were inferior. They completely discounted Michelle's self-destructive behavior, the message it was sending, and her as a person. Their response to her behavior intensified her suffering.

Michelle: What to Ask About

Michelle was desperately suffering. Her current suffering was manifestly expressed: self-medication, substance abuse, self-abuse, arson, and suicidal ideation. Her personhood was so disturbed that she welcomed her own death.

The three caregivers attempted to help Michelle by inviting her to tell her story about her estrangement from her family. Michelle's

relational and social suffering was rooted here. Michelle's mental illness was not named, nor pharmacological treatment of it discussed, and these were essential factors to ask about in considering relief of her suffering.

Michelle's medical and social history showed that she was disconnected from her personhood, indeed, displaced as the teller of her story. Except for the current three therapists, no one had asked about her suffering. Notably, the patient, her family, and the ward staff were all suffering in ways that prevented any of them from asking about any of the others. It is not surprising that therapeutic interventions to date had been ineffective.

Michelle's suffering exceeded the singular competencies of any of the medical and health care disciplines. Team care was needed to achieve partial relief of her suffering. Continued relief of suffering will require long-term therapeutic interventions. This may require challenging decisions to allocate limited resources.

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12. Ethical Considerations for a Multicultural Clinical Workforce

Statement of the Subcommittee Charge

The ethical issues surrounding multiculturalism are most often approached from the perspective of patients' cultural diversity. The effects of a multicultural provider workforce on individuals' approaches to clinical practice have received much less attention. The cultural background of the provider may have a strong impact on the effectiveness and quality of patient care. For example, a provider's cultural background affects the way he or she communicates with patients. One's cultural perspective influences how a provider interprets linguistic nuances, responds to etiquette issues, and how he or she relates to the patient as an individual. Cultural perceptions also affect interactions in the workplace with other health care providers.

The way in which a provider's cultural perspective affects his or her professional judgment can support or undermine the patient's right to self-determination. For example, a provider's expectation about the patient's ability to process information may be based on how he/she views the patient's gender, race, or social class. This may influence the types of treatment offered and the quality of the informed consent obtained. When complex medical and ethical issues are involved, such as a decision to withhold or withdraw life-sustaining treatment, the patient's decision may often hinge on religious or other cultural values. When the patient and the provider have different values or beliefs, it may be difficult for the provider to understand and implement the patient's health care decisions. Different cultural perspectives can also

make it difficult for professional colleagues to agree on the best approach in a given clinical situation.

The subcommittee was asked to identify areas of clinical practice that may be significantly affected by providers' cultural diversity, to consider the ethical issues at stake, and to suggest strategies for addressing and/or resolving these concerns. This report focuses on how differences in cultural perspectives affect individual approaches to clinical practice. We examine the ethical issues that arise when culturally based conflicts occur in the health care setting. Finally, we suggest various ways to address and/or resolve some of the ethical concerns that are raised.

The mix of health care workers, professional staff, and patients that interface in the modern health care setting has become more diverse. Consequently, concern about how to accommodate cultural differences and maintain the quality and consistency of patient care has become more prevalent in medical ethics. When conflicts arise that stem from differences in culture or ethnicity, they affect the relationships of all parties involved in the delivery of health care. Numerous articles in the recent medical literature address the myriad issues raised when there is a conflict between the cultural values and beliefs of the patient and those of the provider. Many authors suggest that in order to become more attuned to the cultural perspectives of their patients, providers must first acknowledge and understand the impact their own cultural experience has on their approach to health care.

VA Demographics

The VA clinical workforce is culturally and ethnically diverse. (See Appendix A.) This is due, in part, to the extensive role the department plays in educating health care professionals. More than half the physicians in the United States receive some portion of their medical training with VA. Many VHA facilities are also affiliated with university medical centers, with which they share educational facilities and resources. Residents, fellows, interns, students, and faculty trained

in various professional disciplines (e.g., dental, medical, nursing, social work) from across the country and around the world rotate through VA health care facilities. VHA also employs a number of health care professionals, such as international medical graduates,[1] who received their initial medical training in countries other than the United States. All of these factors contribute to the mix of professional disciplines and different clinical approaches among VA health care providers. Thus, there are numerous instances where providers of different cultural backgrounds interact in the VA health care setting.

In recent years the VA patient population has also become more diverse. Although more veterans today come from different cultural and ethnic backgrounds, most also share many commonalties. VA patients are primarily male U.S. citizens who were educated and reached maturity in the United States.[2] Most speak a common language and all have a shared experience of military service.

Culture Defined

Culture is defined as "[t]he totality of socially transmitted behavior patterns, art, beliefs, institutions, and all other products of human work and thought characteristic of a community or population."[3] Another definition of culture is: the collective social experiences of a group; experiences that determine the importance group members place on particular elements of their lives. These experiences and values are not static, but evolve and develop over time, as the group migrates and members become exposed to different ideas, environments, and problems. Certain individuals in a group may retain their cultural integrity, while others become acculturated as they integrate into their new surroundings. Cultural experiences and values that have become dormant with time may re-emerge when particular situations, difficulties, or stresses strike a familiar, resonant chord deep within the group's psyche or the individual's subconscious. When this occurs, it may not be readily apparent what aspect of the individual's cultural experience may have caused him/her to react in a certain way.

Culture is reflective of, but is not limited to, nationality, citizenship, geographic location of birth, season or time of birth,

language, manner of dress and bodily adornment, food restrictions or preferences, rituals, etiquette, customs, music, dance, crafts, mythology, artistic expression, and religion. Culture defines the role and importance of subgroups within the society: women, men, children, elders, and those considered less fortunate, such as the sick, the disabled, and the poor. It also determines who in society, for example, the individual or the head of the family or the group, has the authority and responsibility to make decisions. Such diverse elements as the definition of success and the value of time, money, and respect, especially self-respect and "saving face", are important. Additionally, subgroups within the larger group or culture may be influenced by place of residence (urban vs. rural), site, source and level of education, occupation, socioeconomic status, caste, religious affiliation or sect, gender, sexual orientation, primary language or dialect, group self-esteem or ethnic pride, and level of group or individual accomplishment. Each individual then becomes a mosaic of these various forces or elements to which he or she has been exposed over time.[4]

As we examine the different ways in which culture informs and influences daily clinical activities, we may discover shared values, ideals, and virtues within our varied cultural traditions. Increased awareness and understanding of our own cultural perspectives can help renew our sense of professional vocation by calling to mind why we chose health care as a profession. It also creates an opportunity to reaffirm our commitment as providers to maintain the dignity and integrity of VA patients in a manner most appropriate and meaningful to them. As providers become more familiar with the ways in which culture and experience influence individual approaches to clinical practice, they may begin to appreciate more what can be learned from different cultural perspectives. This insight should also help providers become more cognizant of how their cultural perspectives or values may differ from those of their patients.

When Culture is a Source of Bias

When cultures meet in the health care setting, the potential for bias exists on either end of the provider-patient axis. Cultural bias can also intrude on interactions between professional colleagues and between different health care disciplines. This discussion focuses on ethical conflicts that may arise when the provider's cultural perspective differs from that of his or her patient, other providers, or VHA policy. It is important, however, to recognize that cultural diversity of providers also contributes in a positive way to the delivery of ethical care. Examples include cultural concepts such as strong respect for aged persons and for the role of families in care of the sick.

Ethical conflicts may arise when health care providers assume that if a particular approach works for them, it should be ethically acceptable for everyone else. As we alluded to in our previous discussion of culture, there are many factors that affect the delivery of health care. Some cultural practices and beliefs may conflict with concepts of patient autonomy and informed consent that are the ethical foundation for clinical practice in VHA. Problems can arise when a provider's clinical approach is offensive to the patient or contrary to VHA policy, for example, if a provider discourages participation by patients in decision-making.[5] Some VA providers may come from, or identify with, cultures in which:

1. The physician's judgment, decisions, or recommendations are never questioned or refused.
2. The physician or health professional is given the highest honor and respect in the community.
3. The provider is not expected or required to provide information to patients or families.
4. The provider expects to relate only to men, even if the patient is a girl or woman.
5. The accepted perceptions of the meaning of life, death, and illness differ significantly from those of VA patients.[6]

6. It is common practice to use alternative methods of treatment that are not part of the standard therapeutic armamentarium.
7. The provider does not expect to have to obtain the patient's consent to treatment or procedures.
8. The unique rituals or customs surrounding birth and death differ from those of VA patients.
9. Body language or other behavioral clues are more important than spoken or written communication, or certain language or gestures are considered taboo or insulting.
10. The family, group, or community is more important than the individual.

It would be unethical for a VA health care provider to allow cultural attitudes, such as the ones described above, to influence his/her clinical approach in a way that undermines patient autonomy. In addition, if a provider was to adopt a clinical approach that was inconsistent with departmental policy, the provider could be disciplined. Departing from accepted U.S. standards of practice could also increase the provider's risk of legal liability.

Respect for Culture and Cultural Relativism

In discussing how culture affects health care ethics, it is important to note that respect for other cultures, even cultures whose values appear to be at odds with one's own, is not the same as cultural ethical relativism. The approach to any culture, however different it may seem, is based on respect for others: just as all persons are worthy of respect, so are all groups of persons which make up distinct cultures. The value different cultures place on tradition, etiquette, dress, diet, arts and crafts, religion, and other similar domains may be of little moral import. Problems arise, however, when cultural values conflict over moral issues such as limits on individual freedom, treatment of vulnerable groups, responsibility for decision-making, the obligation to tell the truth, and justifications for allowing bodily mutilation or taking of a human life.

Cultural ethical relativism holds that moral norms are solely determined by cultural custom: whatever is the custom of a particular group is moral for the members of that group. The corollary is that there are no moral standards that apply universally to all persons of all cultures at all times. However admirable or repugnant one judges the behavior of persons of a particular cultural group, one outside that culture has no right to make a moral judgment vis-à-vis anyone within that cultural group. This position is contradictory, however, because while cultural relativism denies the existence of universal moral standards, it relies on a universal moral standard of tolerance for all cultural views.

The universal standard of tolerance, as an expression of respect for persons, is discussed in detail in philosophy and ethics literature. There are other universal moral standards as well. The ethical principles of beneficence, nonmaleficence, and justice are often referenced in discussions of clinical ethics. Beneficence refers to the provider's obligation to focus on the patient's welfare and best interest. Nonmaleficence requires the clinician to avoid causing harm. Justice imposes a moral obligation on the provider to treat patients fairly.

The application of the principle of autonomy to clinical ethics is premised on the assumption that an adult patient who has decisional capacity has the right to make his/her own health care decisions. This notion that patients have the right to make treatment decisions is fundamental to the provider-patient relationship in VHA. In order for the patient to freely exercise that right, the patient must understand the nature and consequences of his/her illness and the treatment alternatives, choose from among the available treatment options and communicate that choice to the physician. If the provider's cultural values or beliefs differ from those of the patient and that difference serves to frustrate or undermine patient self-determination, ethical problems occur. For example, if a clinician comes from a culture where only men are allowed to make decisions, the provider may discount the patient's treatment preference because she is a woman. Other commonly recognized moral concepts, such as truth telling, confidentiality, and promise-keeping may also be affected by the

provider's cultural perspective. However, the greatest impact appears to involve issues of autonomy. Accordingly, this paper focuses on how provider cultural diversity affects this aspect of clinical care.

Respect for Persons and Individual Freedom

The basic moral concept that serves as the foundation for much of clinical decision making is "do not deprive freedom"[7] or respect for self-determination or autonomy. The clinical application of this concept is most often perceived in terms of patients' rights. Adult patients who have decisional capacity have the right to accept or refuse any treatment or procedure presented by the provider for their consideration.[8] In the United States, patient participation in decision-making is a recognized part of the patient-physician relationship. Its importance is reflected in the informed consent process. The patient is free to choose, from among the available options, the treatment that is most compatible with his/her values, beliefs and health care goals. Cultural beliefs and values often provide the rationale for the patient's health care decision. This morally based understanding of the patient's right to choose is captured in VHA policy: "patients have the right to consent to and, equally, to decline any treatment, including the provision of life-sustaining treatment." [VA Manual M-2, Part I, Chapter 31, 31.03b.(l).]

The concept of autonomy or self-determination is not limited to patients, but applies to physicians and other health care providers as well. Providers exercise their right of self-determination in the health care setting in at least two fundamental ways: choosing their practice environment and making professional judgments.

Health care professionals have the freedom to choose where they will work. If a provider accepts a particular position at an institution then he/she has an obligation to abide by the institution's policies and fulfill the requirements of the position. In so doing, the health care provider is exercising his/her right of self-determination. Employers, however, may establish policies and procedures that limit or restrict the autonomy of health care providers in the health care setting. This is

similar to the responsibility patients have to comply with the basic rules of the medical facility where they are receiving care. For example, if the health care provider has agreed to practice in VA, he/she has an obligation to do so in accordance with VA rules and regulations. This restraint on absolute freedom does not unduly compromise the provider's autonomy because he/she voluntarily agreed to accept the terms of employment at a particular institution.

Second, within the framework of his/her position, the health care provider has the freedom to use professional judgment. When, for example, a physician determines what treatment options are medically appropriate given the patient's diagnosis and prognosis, he/she must rely primarily on professional training and expertise. A provider is not required to provide treatment that he/she considers medically or morally inappropriate. Most health care institutions, including VHA, allow providers to invoke the conscience clause when the provider is morally opposed to a particular treatment or procedure.[9] An example is a decision concerning life support. VHA policy specifically provides that "[a]ny health care provider may decline to participate in the withholding and withdrawing of life sustaining treatment." (VA Manual M-2, Part I, Chapter 31, 31.08a.) Thus, providers who object as a matter of conscience can refuse to perform certain treatments or procedures, even though the treatment at issue may be medically and ethically appropriate for the patient.

Although the provider's cultural perspective may legitimately influence certain clinical judgments, a provider may not impose his/her cultural values on the patient's treatment decision. Limiting the provider's freedom in this regard is justified because it avoids harm to the patient. Should a similar limitation be placed on providers with respect to cultural conflicts that occur between colleagues and other health care professionals? Can providers maintain their cultural integrity without compromising patients' rights? How does one determine when a provider's actions are culturally based? How should cross-cultural conflicts between the patient and the provider, provider and provider, and the provider and the institution be resolved? Finally, how does the existence of different cultural values, beliefs, and

attitudes among providers affect the overall quality of patient care? The following two case studies highlight these concerns. Although the cases are fictitious, the examples used were compiled from actual incidents that occurred in VA health care facilities.

Case 1

Dr. Mae Savannah is going on annual leave. She asks Dr. Charles E. Winchester III, a colleague in the VAMC medical service, to assume responsibility for the care of her patients while she is away. Dr. Winchester refuses, on the grounds that Dr. Savannah practices "inferior medicine" because she is a woman and is from a different ethnic group and social class. He also points out that she was educated at a second-rate school and has not completed a residency program. Dr. Savannah, whose parents immigrated to the United States from the Caribbean before she was born, received her medical degree from a state university where she was enrolled in a military program. Dr. Savannah completed one year of residency training while in the military. Upon completion of her military service, she accepted employment with VA.

Dr. Winchester contends that his professional standing would be compromised if he were forced to take over the care of Dr. Savannah's patients, to whom, he believes, she gives "second-rate" care. "I could not make up for the deficiency of her care," he says. He insists he should not be burdened with this responsibility, which would jeopardize his professional reputation. Dr. Winchester comes from an affluent community in up-state New York where class distinctions are marked. He was educated at a prestigious New England medical school and completed his neurology residency at a renowned West Coast hospital. The dispute has been brought to the attention of the facility's Ethics Advisory Committee (EAC) for advice and help in resolution.[10]

Ethical, Medical, and Other Issues Raised

1. **Professional Relations** – Dr. Winchester seems focused only on his own reputation. He does not mention the welfare, risks, safety, or best interests of the patients when he complains why he should not have to cover Dr. Savannah's patients. Even though they are

not "his" patients, Dr. Winchester's first concern should be the patients' well-being. Dr. Winchester appears unconcerned with his ethical obligation to act in the patient's best interest (beneficence), to avoid harm (nonmaleficence), and to treat patients fairly (justice).

2. **Courtesy and Respect** – In addition to being concerned about patient welfare, Dr. Winchester must also learn to respect and accept his professional peers. Although his bias against Dr. Savannah is culturally based, he should not be permitted to address a colleague in this fashion.

3. **Quality of Care** – If Dr. Winchester's concerns about the "quality of care" Dr. Savannah provides are genuine, why didn't he raise this issue with the chief of service or quality assurance office earlier? When Dr. Winchester thought that VA patients were at risk, he became professionally and morally obligated to protect them. Dr. Winchester may have been legitimately concerned that Dr. Savannah had only completed a year of residency training. However, the fact that Dr. Savannah is less experienced than he in this medical specialty does not negate Dr. Savannah's competence as a physician.

4. **Discrimination** – Dr. Winchester's refusal to cover for Dr. Savannah in her absence brought to the forefront his prejudice against Dr. Savannah based on her gender, race, and social class. Dr. Winchester cannot allow his cultural bias to interfere with his responsibilities as a VA physician. His first obligation is to ensure the quality of care provided VA patients. Dr. Winchester is also required to act in a respectful and appropriate manner toward his professional colleagues and other health care staff.

Suggested Solutions

The EAC reviewed the case and determined that the ethical issues raised were complicated by cultural conflict. The EAC observed that Dr. Winchester's behavior in this circumstance was inappropriate and unethical. Dr. Winchester should not have attempted to impose his

cultural perspective on his colleague. Furthermore, if he had concerns about Dr. Savannah's professional competence, he should have acted to protect patient welfare. The EAC offered two recommendations: 1) the administrative structure should seek appropriate methods to control or limit the behavior of Dr. Winchester; and (2) education should be developed to enhance cultural sensitivity and increase understanding of the ethical ramifications created by this type of cultural conflict.

Additionally, other appropriate solutions include the following:

1. The matter should be brought to the immediate attention of the chief of the service, who should assign a physician to assume care of Dr. Savannah's patients in her absence.
2. The chief may decide to assign this care to Dr. Winchester. Dr. Winchester cannot be excused under the "conscience clause." There is nothing to indicate that any of the patients have chosen (or refused) treatment that Dr. Winchester finds morally unacceptable. (The chief of service may want to supervise Dr. Winchester more closely to ensure that patients are not being neglected or otherwise jeopardized.)
3. If Dr. Winchester refuses to cover for Dr. Savannah in her absence, he should be counseled extensively—if he still refuses, dismissal may be considered.
4. The chief of service should meet with the rest of the staff to find out if Dr. Winchester's opinions have influenced them and to remedy any resulting misunderstandings.
5. Diversity training should be pursued on the service, with a special focus on ethical implications for patient care, as well as "team-building" exercises.
6. If Dr. Winchester has specific instances of substandard care by Dr. Savannah, the chief of service should appoint a quality assurance team to verify or disprove the allegations and take appropriate follow-up action.
7. Ethics education concerning multicultural issues might include

medical grand rounds sessions or other physician education forums, and facility-wide educational sessions on ethical issues in the multicultural workforce.

Case 2

Peter R. is a 60 year-old veteran, C7-quadriplegic, service connected. He had originally done well and was discharged to his home where he was cared for by his wife. She developed cancer of the pancreas and died within two months of diagnosis. Just before her death, Peter was re-hospitalized with recurrent urinary tract infection. He responded well to treatment, but while efforts were being made to find another caregiver, he developed recurrence. Peter is depressed about his wife's death and asks that no antibiotics be administered so that he can die.

Dr. Manu, Peter's physician, refuses to discuss the matter with him. Dr. Manu is a devout practitioner of his religion, which demands that every spark of life must be nourished and that treatment cannot be withheld even if there is only a remote chance that it might be successful. Dr. Manu is foreign-born and received his medical training outside the United States. He is not very comfortable speaking English or talking about his religious beliefs.

Peter solicits the aid of two nurses he has known for years and asks them to intercede with Dr. Manu on his behalf. Both nurses are from the Philippines and consider nursing a religious vocation. They are disturbed by Peter's refusal to take the antibiotics. They cannot understand why he is "giving up," when with treatment he could recover and be evidence of their excellent care. The nurses also consider Peter a friend and are worried about his state of mind. The nurses think Peter should be seen by a psychiatrist, but they are reluctant to discuss their views with Dr. Manu. In the past, Dr. Manu has become enraged when the nurses asked questions or expressed some concern about his patients. Instead, they contact the facility chaplain and ask him to talk with Peter about his situation. Peter, who is not particularly religious, is reluctant to discuss his concerns with a chaplain. The social worker becomes aware of the problem and asks the Ethics Advisory Committee (EAC) to consult.

Ethical, Medical, and Other Issues Raised

1. **Decisional Capacity** – If Peter is not competent to make health care decisions, then consent for treatment must be obtained from the patient's surrogate. Does the patient's situational depression interfere with his ability to make a valid decision in this case? Has this depression gone unrecognized and untreated by the physician? Would treatment of the depression cause the patient to change his mind about refusing antibiotics and wanting to die?

2. **Autonomy** – Adult patients who have decision-making capacity have the right to refuse recommended treatment, even at risk of death. If Peter is competent to make his own health care decision, then the health care staff should not try to circumvent his choice because they personally disagree with his decision.

3. **Communication** – Dr. Manu's refusal to talk to Peter about his decision to refuse treatment cannot be ethically justified. Dr. Manu does have the right to opt out for reasons of conscience. However, he must make arrangements for another physician to take over the patient's care.

4. **Courtesy and Respect** – Dr. Manu's apparent unwillingness to acknowledge or respond to the concerns of the nurses with respect to Peter's depression is problematic. Dr. Manu must be willing to listen to the concerns and observations of other members on the health care team.

5. **Professional Boundaries** – The nurses' response to Peter's situation indicates that the boundary between professional duty and personal friendship has blurred. How the nurses respond to Peter as a friend may not always be appropriate in the context of the provider-patient relationship. The nurses may be correct in their assessment that the patient's decision-making capacity has been compromised and should raise this concern with the chief nurse if Dr. Manu is not responsive.

6. **Ethics of "Caring"** – This particular ethical approach focuses on what the patient needs given the unique circumstances of his or

her particular situation. Although not necessarily at odds with a patient's rights, for example to refuse treatment or make autonomous decisions, the ethics of "caring" goes beyond traditional notions of autonomy and beneficence and requires that the provider take affirmative steps to address the needs of vulnerable patients in special situations.[11] Peter is especially vulnerable because of his grief. The nurses think the best clinical approach is to help Peter deal with his feelings about his wife's death. This is exemplified by their effort to persuade Peter to meet with the chaplain.

Suggested Solutions

The EAC should talk with the patient, the nurses, the social worker, Dr. Manu, and any other appropriate member of the treatment team. The patient should be evaluated to determine whether he is capable of making health care decisions. If the patient has the capacity to make his own health care decisions, those decisions must be respected. If staff object, they may ask to be removed from the case.

1. Dr. Manu should discuss the consequences of non-treatment with his patient and determine whether a psychiatric consult is indicated. If Dr. Manu believes his religion prohibits him from even discussing non-treatment options with his patient, then he should ask to be excused for reasons of conscience and request that the service chief transfer the patient to the care of another physician.
2. If the patient agrees, the chaplain may be called to provide spiritual counsel and support.
3. Dr. Manu should be counseled to determine why he is reluctant to talk to patients about these issues and to the nurses about their concerns. (Does he consider the nurses "unequals" because of their gender or profession?) Perhaps special training in ethics may be valuable for him.
4. The nurses may need counseling about their decision to contact the chaplain before they were certain that Peter was in agreement. It would have been more appropriate to ask Peter if there was a clergy

member he would like them to contact. They should advise him that the facility chaplain and social work service are available and let Peter make his own decision.

5. The nurses' difficulty in trying to voice their concerns to Dr. Manu should be addressed through appropriate administrative channels—they should move up the chain of command to the chief nurse—who can then contact Dr. Manu's chief of service.

6. All staff on this service might benefit from a workshop or similar training program in ethics and patients' rights and team-building.

Recommendations

As noted earlier, the emphasis in current literature has been to make providers more aware of and sensitive to their patients' cultural beliefs. Providers are encouraged to recognize that their patients' beliefs, values, and health care goals may differ from their own and to avoid imposing their personal perspective on the patient's health care decision. Many of the techniques that have been suggested and applied to guide health care providers in their efforts to care for a culturally diverse patient population can be extrapolated to be relevant in a multicultural provider context. Thus, with slight modification or adaptation, programs developed within the VHA to deal with these ethical issues with respect to patients may serve as a model for our effort to address these concerns from the viewpoint of the provider.

In order to deal effectively with some of the ethical issues they might expect to confront in a multicultural clinical workforce, providers must prepare as follows:

1. Recognize how one's own culture affects behavior and attitudes toward colleagues, other health care staff, patients, and their families.

2. Acknowledge the various ways in which cultural differences can enhance or disrupt the delivery of effective health care.

3. Avoid making generalizations based on limited experience with or exposure to a patient or colleague who comes from a particular cultural group.[12]

4. Learn to listen and observe with an open mind. Providers must also be willing to adapt their skills and be attentive, sensitive, patient, and understanding toward those who have a different cultural perspective.
5. Know how and when to solicit feedback, especially from other members of the treatment team.
6. Be willing to concede power and control to a patient or colleague when the clinical situation demands it.

These recommendations relate in great part to the manner in which the provider is exposed to, trained, or indoctrinated into the nuances of medical care in the United States. The learning activities found in Appendix B can be adapted to meet the needs of different VHA facilities. These activities describe different strategies that may be useful to help providers become more familiar with their own cultural perspectives; recognize how culture can influence the delivery of health care; and develop skills that help them to avoid or resolve ethical concerns posed by cross-cultural conflicts in the health care setting. Employers can support the efforts of individual providers by creating a work environment that is tolerant of cultural differences. Institutional policies should clearly delineate procedures for resolving conflicts that occur. Providers should be encouraged to participate in educational programs designed to help clinicians recognize and respond to ethical dilemmas related to the multicultural workforce. They should also assist in the development of research protocols designed to amass empirical data on the clinical effect of the multicultural workforce on patient care, decision-making, and professional relations.

Conclusion

Providers, like patients, bring their own set of cultural beliefs and values to the health care setting. Each provider's personal cultural experience has some bearing on his or her clinical approach, in much the same way that a patient's beliefs and values influence his/her treatment decisions. Nonetheless, a provider's exercise of freedom and cultural integrity in a clinical setting may legitimately be limited to

protect patients' rights and to ensure compliance with institutional policies. When providers with different cultural backgrounds interact in a health care setting, a number of ethical considerations may emerge. The discussion of these ethical issues in this paper is not exhaustive. The focus is limited to those areas of clinical practice that would most likely be impacted by cultural nuances, such as communications with patients and interactions with other health care providers. This report does not address every potential conflict that might occur in the context of a multicultural provider workforce. The case studies we examined depict plausible conflicts that might occur when providers from different cultural backgrounds interact in a clinical setting. Our intent was to focus on the various ways in which a provider's cultural perspective can influence the delivery of health care and how it can support or undermine patient self-determination. As the VA clinical workforce and patient population become more diverse, it becomes increasingly important for providers to recognize how their own cultural experience, and those of their patients and colleagues, influences the delivery of VA health care.

Appendix A

The following demographic information was extracted from a nationwide survey of full-time and part-time permanent clinical staff at VA health care facilities, VA Workforce Profile by OCC/Levels COIN-PAI 173: 9/30/95. This example is limited to VA nurses and physicians. Information concerning other clinical professions may be obtained from the VA Office of Human Resources Management, Personnel Reports Section (052C1). (Please note that the percentages have been rounded out to the nearest whole number and, therefore, do not reflect the presence of minorities in the workforce where their representation is less than 0.5 percent.)

A nationwide survey of VA health care facilities indicates the following breakdown of racial and ethnic groups among the VA nurse and physician staff.

VA Workforce Profile (Nationwide)

Nurses	Male	Female
White	10%	62%
African American	1%	13%
Hispanic	1%	4%
Asian/Pacific	1%	8%
Native American	0%	0%

Physicians	Male	Female
White	61%	14%
African American	2%	1%
Hispanic	4%	2%
Asian/Pacific	11%	5%
Native American	0%	0%

A survey of the nursing and physician staff at a large West Coast VA medical center reflects a somewhat different mix.

VA Workforce Profile (VAMC Long Beach, CA)

Nurses	Male	Female
White	5%	40%
African American	0%	10%
Hispanic	0%	6%
Asian/Pacific	2%	37%
Native American	0%	0%

Physicians	Male	Female
White	62%	9%
African American	3%	2%
Hispanic	0%	0%
Asian/Pacific	16%	8%
Native American	0%	0%

A survey of the clinical workforce at a hospital located near a large urban center on the East coast shows a different distribution of minorities and women among the nurse and physician staff.

VA Workforce Profile (VAMC New York, NY)

Nurses	**Male**	**Female**
White	4%	30%
African American	1%	18%
Hispanic	3%	12%
Asian/Pacific	2%	29%
Native American	0%	1%

Physicians	**Male**	**Female**
White	59%	20%
African American	3%	2%
Hispanic	3%	2%
Asian/Pacific	9%	2%
Native American	0%	0%

There are essentially no minority nurses or physicians on staff at this rural VA medical center located in the upper Northeast region of the country.

VA Workforce Profile (VAMC White River Junction, VT)

Nurses	**Male**	**Female**
White	13%	86%
African American	0%	0%
Hispanic	0%	0%
Asian/Pacific	1%	0%
Native American	0%	0%

Physicians	Male	Female
White	77%	23%
African American	0%	0%
Hispanic	0%	0%
Asian/Pacific	0%	0%
Native American	0%	0%

Appendix B

Cultural Values and Attitudes of Clinicians

Facilitating Learning Activities

When we reflect on what we think about ourselves and all the communities—family, work, civic, geographic—in which we live, we can appreciate that the way we think, what we think, and what we do is the result of our cumulative experiences in those communities. From these experiences come our cultural perspectives. In the health care setting, as elsewhere, a good understanding and awareness of one's cultural perspective is essential to establishing and maintaining sound relationships—clinician-clinician—as well as clinician-patient. The learning exercises in this section are designed to give clinicians an opportunity to examine their own cultural values and how those values affect their working relationship with other staff and with patients.

Culture is fundamental to the very being of each individual. Thus, it is essential that exploration of cultural issues always take place in a supportive learning environment: one of respect and understanding for each person's cultural perspective. This is the starting-point for preventing or resolving problematic issues.

The exercises in this section are designed to help clinicians:

- appreciate what culture means;
- discuss sensitive cultural issues in a constructive way;

- assess how our individual cultural makeup determines our attitudes and actions toward our fellow clinicians and our patients, particularly our ethical values; and
- use a heightened awareness and understanding of cultural values to prevent or resolve culturally based ethical problems.

Space permits only these brief guidelines to help facilitators plan and carry out the learning activities. More detailed help is available from facility education offices and libraries.

These exercises were adapted from the VA HIV/AIDS National Training Program and are based on accepted principles of adult learning.[1] They are designed to be led by experienced facilitators. Those who are not yet skilled in facilitating adult learning activities should seek the assistance of more experienced colleagues before conducting the suggested exercises.

Every learning activity should begin with a planning session. The first step is for the facilitator and other planners to have a clear idea of why the learning exercise is being presented. The target audience, purpose, objectives, and outcome should be developed for each session, as well as a means of evaluating the extent to which objectives are achieved.

Answers to the following questions should be written down by the planners:

- What specific issue generated the need for this session?
- Who is expected to participate, and for what purpose?
- What are the specific objectives that participants should accomplish in this session?
- How will participants' achievement of the objectives be evaluated?

Facilitators should develop objectives for each learning exercise similar to those that follow. Keep in mind the factors listed immediately above.

Upon completion of these activities, participants should be able to:

- list the main factors that determine culture;
- demonstrate an understanding of how cultural perspectives affect individual health care providers and those with whom they interact in their professional environment;
- recognize the psychosocial implications of coming from a group other than the dominant cultural group in a given professional environment; and
- identify ethical problems that may arise as a result of misunderstanding or ignorance of the cultural backgrounds of staff members who work together.

Culture: What It Is and How It Works

Facilitated Audience Discussion – Large And Small Groups

- **Description** – This exercise gives participants the opportunity to learn what each of them believes are the factors that make up culture, and to work together to articulate a useful definition of culture.
- **Learning Activities** – Large group discussion, then small group discussions of issues raised in large group, ending with a return to the large group. The initial large group activity can stand alone, if time is limited.
- **Materials Needed** – Flip chart, markers, and masking tape preferred; blackboard will suffice.

Large Group Discussion (60 minutes)

Introduce the Session (5 Minutes)

If this is the first time the group has been together, the facilitator should introduce him or herself and give the participants the opportunity to introduce themselves.[2] Use the introductions to establish an informal environment that will support open discussion.

Tell the group that you would like to guide them through an exploration of what we mean by culture, how culture affects our professional and personal lives, and how cultural values influence our clinical behavior. Highlight comments on ethical issues.

As a basis for the discussion that follows, ask those in the group to reflect on their family, community, and school experiences, as well as their professional experience.

What is culture? (15 minutes)

- Ask the group, "What are the elements that make up culture?" You are asking for factors—not a definition—that comes later. Encourage spontaneous responses—avoid leading individuals to think that they have to "second guess" what you are looking for—you want the group to go on to work with a list generated by its own members.
- List individual responses on the flip chart—do not discuss them yet. If responses are slow in coming, stimulate responses with questions. Have someone tape the flip chart pages to the wall as you fill them up with cultural factors. Stop soliciting responses after four or five minutes.
- Ask if everyone agrees that the factors listed are all part of what we mean when we say "culture." If there is agreement or disagreement, ask why. Try to guide the group to discover if the members can work toward a consensus, but do not force it—discussion can bring up important nuances in perceptions of culture.
- Ask various individuals in the group if they can use what has been discussed so far to come up with a working definition of culture. Continue to use the flip chart. Complete this part of the activity by coming up with a working definition that is useful for everyone in the group.
- Briefly restate what the group has defined as culture. Ask each person to reflect on what his or her culture is and how it may affect their outlook and behavior.

What is the culture of your professional environment? (10 minutes)

- Now that the group agrees on the overall concept of what culture is, next ask individuals to describe the cultures represented in their professional environment. A good starting point is to spend a few minutes asking what participants feel makes up their professional environment; we are talking about the clinical staff as well as the patient demographics of the medical center or outpatient clinic. The group may bring up other factors not previously considered.

Are there factors in your cultural background that make you comfortable or otherwise help you when working with the staff and patients in the professional environment? (10 minutes)

- List the factors on a flip chart. Ask how they help, how they are viewed as strengths. If some in the group bring up factors that you feel are outside the realm of culture, ask for additional details.
- Summarize. Are there commonalties? What can we learn from these factors?

Are there factors in your cultural background that make you uncomfortable or otherwise hinder your work with the staff in your professional environment? (10 minutes)

- List the factors on a flip chart. Ask how they hinder, if they are viewed as weaknesses. If some in the group bring up factors that you feel are outside the realm of culture, ask for additional details.
- Avoid having an individual or the group belabor a negative issue, which is always easy to do.
- Summarize. Are there commonalties? What can we learn from these factors?

Among the cultural factors that we have listed, which are the ones that most affect the ethical aspects of our practice? (10 minutes)

- Focus attention on the cultural values that determine our attitudes toward issues like respect for colleagues and for patients,

autonomous patient decision-making, power and vulnerability, and gender issues.

Summarize the Session (5 minutes)

- Briefly restate what the group tried to accomplish. Summarize what the group did accomplish, stressing the connection between cultural values and the ethics of clinical encounters. If there is unfinished business, discuss what the group can do to take care of it.
- If this was a stand-alone large group session, it ends with the facilitator's summary. If this session will be followed by small group sessions, give the group directions on what to do.

Small Group Discussion (25 minutes)

- **Preparation** – The facilitator may use some random method of assigning participants to groups, such as counting off by the number of groups desired (with all the participants that are "1" going to one group, "2" going to the second group, and so on), or by random placement of colored dots on handout materials or name badges given to participants (participants having the same color going together). The facilitator should be aware that there may be reluctance on the part of some or all of the participants to join small groups and to make this process as comfortable as possible.
- **Materials** – Flip chart, markers, and masking tape preferred; notepads will suffice.

Ask each group to select someone to briefly report in the concluding large group session.

From the cultural factors identified during the large group discussion, direct the small groups to select one or two that they feel have most strongly influenced their ethical judgments in clinical encounters.

- Have they found these factors to be a help or a hindrance?
- How do they deal with the cultural factors that they believe hinder their professional relationships?

- How can they help other clinicians to appreciate and understand how these factors may affect professional behavior?

Large Group Discussion (15-30 minutes)

- In the large group, each small group reporter will share one cultural factor that the group found to be ethically problematic and strategies that members of the group have identified that can help to resolve issues surrounding this factor. Each reporter should deal with only one factor that has not been mentioned by previous reporters: this avoids redundant reports and allows each group to bring up a fresh issue. The facilitator should try to keep reports focused and concise. Total time for the reports depends on the time available and the number of groups reporting.
- The facilitator asks if there are any issues on which anyone would like to comment before closing, and then makes a brief summary comment on what the group was attempting to do in this exercise, and how well it was done.

Cultural Perspectives of Others

Panel Presentation and Discussion[3]

- **Description** – Participants have the opportunity to hear, firsthand, how the culture of clinicians affects how they relate to their colleagues and patients, and how the dominant cultures in their health care environment affect them.
- **Learning Activities** – Panel discussion led by a moderator, with questions and comments from the audience, followed by large or small group discussions.
- **Materials Needed** – Table and chairs in front of the room for the panel, microphones and speakers, depending on size of room and number in audience; flip chart and markers may be useful in reinforcing main issues and in focusing discussion; areas for small group discussion activities, if included.

- **Preparation** – Panelists should be chosen for their willingness to be self-disclosing to a moderate degree and should be able to express themselves clearly. They need not be experienced presenters, since the moderator will guide them. A panel of three of four persons is optimal. The suggested times may be altered to suit the total time available, the number of panelists, and the interests of the participants.

  Prior to the session, the moderator should spend some time with the panelists to clarify the focus of the panel, review the type of questions they are likely to be asked, and to alert them as to how the moderator will guide the session.

  "Ground rules" should be agreed to before the session and should be restated to the audience as the panel begins:

  - Panelists or members of the audience will not violate the confidence of patients or colleagues in recounting their experiences;
  - Those in the audience are asked to be sensitive to the feelings of panelists and others in the audience when asking questions of the panelists;
  - Those in the audience may ask any reasonable question and panelists may decline to respond to any question;
  - The moderator will maintain the focus of the discussion and may defer questions to a later time.

Panel Presentation (30 minutes)

The moderator introduces him or herself, states the purpose of the session with its focus on culture and ethics, and states the ground rules. The ground rules may be posted on a flip chart as well. Next the moderator briefly introduces the panel—each of the panelists should add to the introduction as he or she begins his or her comments.

Large or Small Group Discussion (25 minutes)

Following the panelists' comments, the moderator may ask participants to respond to the following, or similar questions. If the audience is large, more productive discussions are likely in groups of four to six persons—the moderator can circulate among the groups and each of the panelists can be invited to join a group, if they wish.

1. What feelings did you experience while listening to the panel?
2. What issue affected you the most?
3. What are your concerns about relating in a constructive way with co-workers of different cultures?
4. What are your concerns about respecting your own cultural values and perspectives in your health care environment?
5. What approaches can you take if clinicians holding different cultural values appear to be in conflict with each other or with patients over factors such as race, gender, professional status or social class?

The moderator may close the session by asking the small groups to reassemble, soliciting a few brief comments on what the participants thought of the activity, and making a brief closing comment.

Notes

[1] Some international medical graduates are foreign-born. Others are U.S. citizens who are graduates of foreign medical schools.

[2] Nelson WA, Law DH. "Clinical Ethics Education in the Department of Veterans Affairs." *Cambridge Quarterly of Healthcare Ethics* 1994;3:143-148.

[3] *The American Heritage Dictionary of the English Language*, New College Edition. Boston: Houghton Mifflin, 1976.

[4] Fejos describes culture as "the sum total of socially inherited characteristics of a human group that comprises everything which one generation can tell, convey, or hand down to the next; in other

words, the non-physically inherited traits we possess." Another way of understanding the concept of culture is to picture it as the luggage that each of us carries around for our lifetime. It is the sum of beliefs, practices, habits, likes, dislikes, norms, customs, rituals, and so forth that we have learned from our families during the years of socialization. In turn, we transmit cultural luggage to our own children. The society in which we live—and other forces, political, economic, and social—tend to alter the way in which some aspects of a particular culture are transmitted and maintained. Spector, RE. *Cultural Diversity in Health and Illness*. 2nd ed. Norwalk, CT: Appleton-Century-Crofts, 1985:60-61.

5 See, VHA Handbook 1004.1, "Informed Consent."

6 These are subject areas where differences in cultural values and beliefs can have a tremendous impact on patient care. The question of how a provider's attitudes concerning life, death, and illness, for example, influence the treatment options offered to patients should be examined more fully in a separate paper.

7 Gert B. *Morality: A New Justification of the Moral Rules*. New York: Oxford University Press, 1988.

8 If a patient does not have the capacity to make health care decisions, consent must be obtained from the patient's surrogate.

9 This concept is based on the premise that a provider should not be forced to provide treatments or procedures to which he or she is morally opposed. Questions have been raised about the use and scope of the conscience clause, for example, in circumstances where the patient's access to other health care providers is limited. The committee maintains that the practice of allowing providers to opt out for reasons of conscience is justifiable and should be continued.

10 Cross-cultural problems that occur in the health care setting may be presented to an ethics advisory committee for consideration. However, in some situations it may be more appropriate to address the matter through administrative, supervisory, or personnel channels.

[11] Davis AJ. "Are There Limits to Caring?: Conflict Between Autonomy and Beneficence," in *Ethical and Moral Dimensions of Care*, Leininger M., ed. Detroit: Wayne State University Press, 1990:25-32.

[12] Providers must resist the temptation to stereotype based on skin color, surname, gender, age, accent, or style of dress. No one physician, for example, is an exact cultural match with every other physician from the same cultural group.

Appendix Notes

[B-1] The effect such educational programs might have on the resolution of culturally based conflicts that occur in the health care setting has not been studied. Nonetheless, we are confident that efforts that encourage providers to openly discuss their cultural differences and how they enhance or disrupt the delivery of health care will prove beneficial.

[B-2] Facilitation or training guides may be consulted for ideas on effective ways to conduct introductions.

[B-3] If a panel discussion is not feasible, case studies or role-playing scenarios that depict culturally related ethical problems can be used to stimulate discussion. Facilitators can adapt the ground rules and discussion questions to fit these formats. The cases described in this paper can be read by participants or can serve as the foundation for role plays.

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13. Professional Conflicts of Interest for VHA Clinicians

Clinicians employed by VA facilities have a potential conflict of interest intrinsic to the care of their patients. On the one hand, clinicians such as physicians, dentists, nurse practitioners, clinical nurse specialists, physicians' assistants, and clinical social workers have the ethical responsibility to make health care decisions that represent the best interests of their patients, without regard for how such decisions impact on VHA. This ethical duty arises from the fiduciary responsibility of clinicians as professionals to grant primacy to the best interests of their patients.

On the other hand, as employees of a fixed-budget health care organization, VHA clinicians have the administrative duty of stewardship: to act responsibly to conserve scarce medical resources to preserve the good or equality of all patients within the system. If, in an attempt to "do everything possible" for a given patient, a clinician were to use the system's scarce medical resources irresponsibly, other patients within the system might no longer be able to receive a needed resource and be harmed. As a result, even though one patient might receive a marginal benefit, more net harm than good could result to the totality of patients within the system. Therefore, such an action, even though beneficently motivated by a clinician in an individual case, could be viewed as unethical.

The conflict of interest becomes most explicit in the situation in which a clinician believes that an expensive and scarce test or therapy has a small, marginal value to a given patient, but knows that the

system cannot afford to provide the test or therapy to all patients in similar situations. To provide the test or treatment of small, marginal value fulfills the clinician's fiduciary duty to the patient but simultaneously violates the clinician's stewardship duty to the system. To which master—the patient or VHA—does the clinician owe primary allegiance? How should such conflicts of interest be resolved?

Charge

The Subcommittee on Professional Conflicts of Interest for VHA Clinicians was charged by the VHA Bioethics Committee to consider how and by what criteria VHA clinicians should resolve intrinsic professional conflicts of interest between their fiduciary duties to individual patients and their stewardship duties to the population of patients. The subcommittee restricted its scope to professional conflicts of clinicians that occur within the VHA system.[1]

Definition of a Conflict of Interest

One commonly accepted definition provides: "A person P has a conflict of interest if and only if: 1) P is in a relationship with another requiring P to exercise judgment on another's behalf and 2) P has a (special) interest tending to interfere with the proper exercise of judgment in that relationship."[2] Another definition that focuses on the subset of financial conflicts of interests provides: "A conflict of interest is a set of conditions in which professional judgment concerning a primary interest (such as a patient's welfare) tends to be unduly influenced by a secondary interest (such as financial gain)."[3] The primary interest for clinicians is dictated by professional duties. In the case of the physician, it is clear from codes of professional ethics that the physician's primary interest should be the welfare of the patient.[4] Indeed, one of the features that distinguishes medicine as a profession and not a business is the primacy of the patient's interests over the proprietary interest of the professional.[5] Because non-physician clinicians function in essentially the same clinical role as do physicians, they have the same primary professional fiduciary duty to patients.

Secondary interests of clinical professionals include personal

financial interests, administrative institutional duties, teaching and research duties, public health duties, and duties to self and family. These are legitimate, necessary and desirable interests. It is only when they conflict with the primary duty to patients that they become a problem for the clinical professional. Lesser degrees of conflicts of interest may arise when the secondary duties conflict with each other.

In this report we use the term "conflict of interest" in its broadest sense according to the first definition. Thus, the term does not refer solely to financial conflicts of interest in which a clinician stands to gain monetarily by a certain course of actions, but includes conflicts of professional role responsibilities and conflicts of professional obligations. Indeed, the conflicts of professional roles and obligations are a more common and vexing source of conflicts of interest for VHA clinicians than the more narrowly defined financial conflicts. For the sake of simplicity, we will use the term "conflicts of interest" to refer to all of these concepts.

Roles of a VHA Clinician

Clinicians in VHA facilities simultaneously may assume a number of different roles and responsibilities during the course of their employment.[6] In addition to providing health care to patients, the clinician is an employee of VHA and of the Federal government. Clinicians also may teach, conduct research, and serve in various administrative capacities in the medical center and affiliated medical or professional school. These multiple roles are usually complementary and compatible but may compete and conflict in certain situations.

1. **Patient care provider** – In providing health care, a clinician has the professional responsibility to act in the best interest of the patient. Clinicians are fiduciaries and so have fiduciary professional responsibilities.[7] The role of patient care provider encompasses not only providing conscientious and competent health care, but also communicating to the patient the available diagnostic and treatment options (including options that are available outside the VA system), and recommending those that the clinician believes are

best for the patient. Through a process of shared decision-making the patient and clinician arrive jointly at the optimum care plan. A clinician's fiduciary duty to patients is the foundation of the clinician-patient relationship and is independent of the patient's socioeconomic, physical, or mental status.

2. **Clinical professional** – Clinicians have a professional duty to maintain the integrity of the clinical professions. For example, physicians and other clinicians have the duty to identify and report impaired physicians, both to promote their rehabilitation and to protect patients who may be harmed by them. Similarly, physicians have the duty to report fraud, professional misconduct, clinician incompetence, and patient abandonment.[8] Physicians and other clinicians have a professional duty to maintain the quality of medical care for the betterment of patient welfare.

3. **Patient advocate** – Patient advocacy is a role distinct from that of patient health care provider. The role of patient advocate encompasses the duty to assist the patient to receive equitable treatment in the patient's dealings with the VA bureaucracy, health insurers, lawyers, disability determination bureaus, community health care resources, and other administrative bodies. Often, the duty of patient advocate requires close communication with the patient's family.

4. **Employee of VHA and the Federal government** – As an employee of a VA facility, the clinician is obligated to follow the rules and regulations of the institution and the agency. Many rules are designed to equitably distribute scarce medical resources to patients, or to provide such resources in compliance with applicable law. At times, such rules may limit or proscribe the tests or treatments available to a specific patient and thereby create a conflict of interest. Clinicians need to be aware of potential conflicts between institutional policy and the best interests of individual patients. Specific inducements in the system that reward hospitals that increase outpatient care, for instance, could influence judgments concerning the need for inpatient care in individual cases. VHA clinicians also may be required to make medical

decisions that influence administrative determinations about compensation or benefits. At times, such decisions may limit access to certain care, treatment or service. Such decisions may conflict with a clinician's role as patient care provider and patient advocate.

5. **Protector of public health** – Clinicians have a professional responsibility to promote public health. The protection of public health encompasses efforts to contain and cure communicable diseases; to prevent abuse and violence; to enhance home, workplace, and transportation safety; to enhance food, water, and air purity; and to protect third parties known to be at risk. The responsibility to contain communicable diseases and to protect third parties known to be at risk for contracting a disease from an infected patient may at times conflict with the duty to maintain patient confidentiality, one of the primary patient care responsibilities of clinicians. The obligation to inform public health officials about a patient's infection with a communicable disease, whether or not consent has been provided, conflicts with the duty to maintain patient confidentiality.

6. **Researcher** – VHA clinicians participating in research have an obligation to ensure the integrity of the research and, in the case of human subjects research, to follow established guidelines for engaging in human experimentation. Conflicts may arise when what is best for the research project is not in the best interest of the patient. A conflict may also arise when the only way to access an emerging treatment is through a research protocol. This may present a problem if a patient seeks a particular treatment and may benefit from the treatment, but is not an appropriate candidate for the research protocol. A financial conflict may be present if a clinician has an economic interest in obtaining subjects for a research protocol.

7. **Responsibility to advise on procurement of equipment and medications** – A VHA clinician may have a responsibility as an expert to recommend the selection of equipment or medications to be procured. Examples are the chairperson of the Pharmacy and Therapeutics Committee or the chief of a specialty service such as

radiology. This expert role exposes the clinician to subtle and/or monetary influences in attempts to unduly influence the decision. Acceptance of gifts or gratuities or favors from any manufacturer represents a conflict of interest if the clinician is in this key role.[9]

8. **Prescriber of drugs and equipment** – The VHA clinician routinely prescribes drugs and orders equipment such as prosthetic devices. A conflict of interest may exist between what is the best drug or piece or equipment for the patient and the inclinations of the clinician as influenced by various experiences including possible favors, meals, trips, and honoraria given by manufacturers in order to promote their products. This situation is exaggerated by the absence of adequate funds within the VA to conduct educational programs. As a result, pharmaceutical companies now often play an important role in funding educational events, increasing the opportunity for inappropriate influence on VHA clinicians.[10]

9. **Educator** – Many VHA clinicians are faculty members at affiliated medical schools or other professional schools. A clinician, functioning in the role of an educator, has a set of responsibilities and obligations to students, faculty colleagues, and the school administration. Such roles, at times, may conflict with clinicians' primary responsibility to patients' welfare if the time commitments or loyalty between the medical/professional school and VHA conflict.

The national focus on managed health care delivery has had a significant impact on the various roles assumed by VHA clinicians. For example, clinicians have an explicit responsibility to use scarce resources efficiently, particularly in a setting where the institution mandates certain procedures or approaches to health care. Yet, the clinician maintains the primary responsibility to provide the best care possible to his or her individual patient. VHA clinicians must strike a balance between following institutional procedures to avoid waste, use scarce resources efficiently, and maximize the care provided to the veteran population as a whole, while providing the best care possible to an individual patient.[11]

Ethical and Legal Duties

Both ethical and legal principles require that certain interests or obligations take precedence over others. Therefore, when conflicts of interest and obligations develop, it is helpful to review the ethical principles and legal obligations that underlie professional duties. This section briefly discusses the similarities and differences between ethical and legal duties.

Four principles guide traditional medical ethics: the principle of nonmaleficence, prohibiting the commission of harmful acts; the principle of beneficence, encompassing an obligation to help others further their interests; the principle of autonomy, recognizing the individual's right to evaluate and choose his or her own course of action; and the principle of justice, encompassing concepts of fairness and desert (i.e., deserved reward and punishment).[12]

Ethical standards for physicians generally dictate that their primary ethical duty is to further the best interests of the patient, embodying the principles of autonomy, nonmaleficence, and beneficence.[13] For example, the American Medical Association Code of Medical Ethics states that "[a] physician has a duty to do all that he or she can for the benefit of the individual patient."[14] Similarly, the Code states that patient welfare should take priority in situations where a hospital's economic interests conflict with patient welfare, and that the physician's primary consideration should be the care of the patient. It follows that other non-physician clinicians who are acting in expanded roles to provide health care to patients are bound by the ethical duty to place the best interests of the patients ahead of other conflicting interests.

Similarly, the law provides that a clinician's primary legal duty is to place the best interests of the patient over all competing considerations. This legal obligation is based on the development of the standard of care in medical malpractice claims. There is no absolute standard of care against which a clinician will be evaluated during the course of a medical malpractice claim. Rather, the legal standard of care to which a

clinician is held is developed during the course of a trial on the basis of the expert testimony provided.[15] Although this legal standard of care can vary from case to case, the standard that is ultimately developed at trial always is oriented to the interests of the patient, and it requires the clinician to place the patient's interests above any competing interests and to exercise due care in providing services to the patient.[16]

The standard of care also is based on the idea that a physician or other clinician is acting as a fiduciary to the patient. The fiduciary relationship requires the clinician to act in the patient's best interests and to put such interests above most other considerations. The role of a fiduciary prevents the clinician from paying excessive attention to the societal interest in conserving resources when caring for a patient.[17]

There may be a question as to whether a particular course of treatment is beneficial, or whether a clinician's actions reflect the level of skill required to meet the community standard of care. However, the legal standard generally will not allow for withholding beneficial treatment or treatment that has at least a reasonable probability of benefiting the patient. A standard of care that allowed the withholding of beneficial treatment "would be a stark and unacceptable departure from the requirement that the physician exercise a certain level of skill and care in the treatment of patients and act in their best interest."[18] Thus from a legal as well as an ethical point of view, a clinician has a duty to act in the best interests of the patient and to give primacy to the role of patient care provider.[19]

Certain ethical and legal duties are also imposed on employees of the Federal government by statute and regulation. Specifically, as employees of the Federal government, VHA clinicians are required to comply with ethical rules governing employees of the executive branch of government. These rules govern a wide range of activities and topics, including accepting gifts, conflicting financial interests, impartiality in performing government service, misuse of government position, use of government property and official time, and activities outside of one's government employment.[20] A number of criminal laws pertaining to bribery, graft, and conflicts of interest are also applicable to certain employees of the Federal government.[21]

When the Roles Conflict

Usually, the multiple roles of VHA clinicians are compatible and do not conflict. The following examples may help clarify the nature of the conflicts when they do occur.

Rationing of MRI Scans

Confirmation of the clinical diagnosis of suspected epidural spinal cord compression from metastatic carcinoma is best accomplished by obtaining MRI scanning of the spine. In centers where MRI is available, it has essentially replaced myelography for this indication because MRI is less invasive, safer, and more diagnostically sensitive and specific than myelography.[22] However, many VHA facilities do not have on-site MRI units. In such VHA facilities, clinicians ordering tests to confirm the clinical diagnosis of epidural spinal cord compression from metastatic carcinoma must decide whether to send the patient off-site for MRI or to ask an on-site radiologist to perform myelography. Because acute spinal cord compression is a medical emergency, most often there is not time to travel to a VHA regional MRI facility so a community MRI must be obtained on a fee basis. The budget for community fee-basis MRI is severely limited, and most VHA facilities require approval of the chief of staff before permitting the test. Clinicians, therefore, are asked if the test is absolutely necessary or if myelography would suffice. In many cases, clinicians decide to opt for myelography because it is available, even though it is less desirable than MRI.

In these VHA facilities, oncologists, internists, neurologists, orthopedists, and other clinicians facing this dilemma frequently come to understand that MRI is rationed and to subsequently incorporate that fact into their practices. In these settings, they may alter their ordinary practices and order myelography routinely. Such decisions represent a conflict of interest (obligation) because that which is best for the system (conserving scarce financial resources) may not be that which is best for the individual patient. Residents rotating successively through VHA facilities and university hospitals often can see such dual standards of practice most starkly.[23]

Choosing a Less Expensive Drug

The pharmacies of VHA facilities have limited budgets. Pharmacy and therapeutics (P&T) committees of each facility have the difficult task of choosing those medications to place on the formulary and to be made available to patients. P&T committees often choose medications within similar classes that are less expensive.[24] Most facilities have in place a process to allow clinicians to request a drug that is not included on the facility formulary.

For some therapeutic indications, expensive non-formulary medications may have marginal benefits over less expensive formulary medications. For example, valproate and divalproex are both preparations of the anticonvulsant valproic acid. Divalproex produces less gastrointestinal irritation than valproate, but costs significantly more.[25] Many VHA pharmacies stock valproate but not divalproex because, in the opinion of those on the P&T committee, the marginal benefit does not justify the extra cost. Clinicians choosing valproic acid in this situation must compromise and prescribe valproate, knowing that divalproex is likely to be marginally better for the patient. This action represents a conflict of interest (obligation) between the clinician's fiduciary and stewardship duties.

Academic Responsibilities vs. Patient Care Duties

VHA is actively involved in the education of health professionals as part of the mission of the agency. The majority of VHA patient care facilities are affiliated with at least one medical or other health professional school. Nationwide, over 1,000 professional schools of varying types are affiliated with VHA facilities.[26] Many VA clinicians serve as faculty at a professional school. In many cases, the clinician's salary is shared between the VHA facility and the professional school, in recognition of the dual responsibilities. VHA clinicians serve important professional school functions, such as teaching students, preceptoring, supervising residents, conducting research, and serving on professional school committees. It is generally accepted that such affiliations improve the quality of patient care by attracting a higher

quality of clinician to VHA facilities than otherwise might be recruited. However, the dual roles of a VHA clinician can represent a conflict of interest (role or obligation) when time devoted to professional school responsibilities must be shared with patient care duties.

Financial Interest in Research

A clinician's research responsibilities and associated financial interests may either conflict, or present the appearance of a conflict, with the clinician's obligations to the patient. This is a conflict of interest in its narrower, financial sense. The potential for such a conflict is demonstrated in a case where a patient alleged that a physician breached his/her fiduciary duty by failing to disclose his/her potentially conflicting research and economic interests in the patient's cells.[27]

A patient with hairy-cell leukemia was evaluated by a physician who collected blood and tissue samples and confirmed the diagnosis. The physician recommended a splenectomy, which was subsequently performed. The patient returned to the physician for follow-up visits that involved the collection of additional blood and tissue samples.

Unbeknownst to him, the cells that had been removed from the patient were being used for research. The cells were unique and had potential scientific and commercial value. The research resulted in the development of a potentially lucrative patented cell line. The court's opinion states that the physician benefited financially from the development of the cell line.[28]

When the patient learned of the research, he sued the physician, the regents of the university, a university researcher, and the licensees of rights to the patented cell line and its products. The patient alleged, among other things, that the physician and other defendants failed to disclose their research and economic interests in his cells before obtaining his consent for medical procedures. The California Supreme Court held that the lower court could proceed on that aspect of the lawsuit alleging a breach of fiduciary duty. The court specifically held that: "[a] physician who is seeking a patient's consent for a medical

procedure must, in order to satisfy his fiduciary duty and to obtain the patient's informed consent, disclose personal interests unrelated to the patient's health, whether research or economic, that may affect his medical judgment."[29] This case exemplifies a situation where a patient believes that a clinician's fiduciary duty conflicted with the physician's research and financial interests.

Resolution of the Conflicts

The resolution of a VHA clinician's professional conflict of interest has three dimensions: 1) avoidance of the conflict when possible; 2) disclosure to the patient when the conflict cannot be avoided; and 3) development of practice guidelines both to minimize the occurrence of unnecessary professional conflicts and to maximize the disclosure to patients of necessary conflicts.

The narrower financial professional conflicts may be avoided by strictly adhering to a code of professional conduct that forbids unethical behavior. For example, most codes of clinical professional conduct regulate or forbid clinicians from accepting gifts, gratuities, or kickbacks from agencies with whom the clinician interacts in the care of patients.[30] Conflicts of accepting gifts, of financial interests, of impartiality in performing government service, of misuse of government position, of use of government property and official time, and of activities outside of one's government employment can be avoided by adhering to the *Standards of Ethical Conduct for Employees of the Executive Branch*.[31] Clinicians can avoid conflicts of teaching vs. patient care responsibilities by scrupulously protecting the time that is supposed to be devoted to patient care or by providing appropriate compensatory patient care time when the clinician must spend time away from patient care.

Some conflicts, such as those between clinicians' fiduciary and stewardship duties, remain unavoidable, especially as we move into the managed health care delivery model. Here, clinicians have the duty to disclose the conflicts to patients. Patients should be told in advance that VA is moving into a managed health care delivery model, and that

this new focus on managed health care delivery, when combined with fixed institutional budgets, necessitates rationing of some types of expensive, scarce tests and treatments. Patients should be notified that certain elements of their diagnostic testing or treatment may be different in VHA from what they might be in some other practice setting. For example, a patient in a managed health care delivery system such as VA may not have access to certain drugs or procedures that would be provided in other settings. The marginal utilities of the rationed items should be described, particularly where such items would be available in other health care settings. Patients should be notified when as a result of the managed care practice certain procedures are provided selectively, so they are informed and can take necessary action to procure alternative medical care if they are able and so desire.

Clinicians within VHA should work to develop institutional guidelines aimed at minimizing the conflicts and disclosing them effectively. The guidelines should be developed by clinicians, with physicians playing a leadership role. Development of guidelines should be an ongoing process. The guidelines should be based upon accepted standards of medical practice as articulated through clinical practice guidelines developed or endorsed by medical societies. The guidelines should take into account evidence-based outcomes of medical treatment and aim to maximize the quality of care provided by clinicians.[32] Physicians and other clinicians should be presented with these guidelines on beginning employment at VHA and endorse them as a condition of accepting employment. Patients should be aware that their clinicians, in caring for them, will be following practice guidelines based upon efficacy and cost.

Recommendations

1. VHA clinicians should avoid financial and other conflicts of interest in their practice of patient care, education, and research. Many such conflicts can be avoided by adhering to codes of professional conduct and codes of ethics accepted by their profession, and by following the requirements of the *Standards of Ethical Conduct for Employees of the Executive Branch*.

2. In cases where financial and other conflicts of interest involving patients are unavoidable, the conflict should be disclosed to the patients. For example, if a local policy restricts or limits the availability of a particular treatment or therapy, the patient should be informed of the restriction.

3. VHA facilities should use clinical practice guidelines or critical pathways developed by medical specialty societies that are evidence-based, appropriately consider efficacy and cost factors, and are designed to improve the quality of care. There are clinical situations that occur commonly in VHA facilities for which nationally accepted practice guidelines or critical pathways do not exist. In these situations, VA should develop appropriate clinical practice guidelines.

4. Clinicians working at VHA facilities should be involved in the development and implementation of clinical practice guidelines and should be willing to endorse the clinical practice guidelines and critical pathways they will be expected to follow.

5. A system is already in place to educate employees regarding their obligation to avoid certain conflicts of interest under the *Standards of Ethical Conduct for Employees of the Executive Branch*. The areas covered by these regulations include accepting gifts, conflicting financial interests, impartiality in performing government service, misuse of government position, use of government property and official time, and activities outside of government service. These regulations, however, do not address many of the conflicts of obligation or role that are unique to clinical settings. VHA should develop a mechanism to alert and educate clinicians about the

existence of conflicts of role and obligation and the appropriate means of resolving such conflicts. This could be achieved through an information bulletin, a satellite conference, or in a workshop setting. Ethics Advisory Committees at VA facilities could be a potential resource to help resolve issues that arise in clinical settings.

Notes

1 The broader subject of professional conflicts of interest among physicians in other health care settings was recently the subject of a thorough scholarly analysis. See Rodwin MA. *Medicine, Money and Morals: Physicians' Conflicts of Interest*. New York: Oxford University Press, 1993.

2 Davis M. "Conflict of Interest Revisited." *Business and Professional Ethics Journal* 1993(winter);12:21-41.

3 Thompson DF. "Understanding Financial Conflicts of Interest." *N Engl J Med* l993;329:573-576. A more general and rigorous definition of conflict of interest was provided by Davis, as noted above.

4 See American Medical Association. *Code of Medical Ethics*. Chicago: American Medical Association, 1994; and Noy S, Lachman R. "Physician-Hospital Conflict Among Salaried Physicians." *Health Care Manage Rev* 1993;18(4):60-69. Nurses and social workers have similar codes of ethical obligations to patients. See American Nurses' Association. "American Nurses' Association Code for Nurses," in Benjamin M, Curtis *J. Ethics in Nursing* 3rd ed. New York: Oxford University Press, 1992; National Association of Social Workers, Inc. *Code of Ethics of the National Association of Social Workers*. Silver Spring, MD: National Association of Social Workers, Inc., 1990.

5 Reed RR, Evans D. "The Deprofessionalization of Medicine: Causes, Effects and Responses." *JAMA* 1987;258:3279-3282.

6 Mirvis DM. "Physicians in Organizations. Dilemma of the Academic VA Staff Physician." *Arch Intern Med* 1990;150:1621-1623.

[7] Marc Rodwin recently analyzed the fiduciary role of physicians and the conflicts of obligations of physicians as fiduciaries. See Rodwin MA. "Strains in the Fiduciary Metaphor: Divided Physician Loyalties and Obligations in a Changing Health Care System." *Am J Law Med* 1995;21:241-257.

[8] These duties are described in detail in, for example, American College of Physicians. *American College of Physicians Ethics Manual*, 3rd ed. *Ann Intern Med* 1992;117:947-960.

[9] *The Standards of Ethical Conduct for Employees of the Executive Branch*, as well as certain criminal laws, may be violated by the acceptance of gifts and gratuities. 5 C.F.R. Part 2635; 18 U.S.C. §§ 203, 208. The procurement integrity laws may also be implicated if a clinician, acting as a procurement official, accepts gifts and gratuities. 41 U.S.C. §§ 401-424. See discussion, *infra* notes 20 and 21.

[10] See discussion, *infra* notes 20 and 21.

[11] See Kassirer JP. "Managed Care and the Morality of the Marketplace." *N Eng J Med* 1995;331(1):50-52. Menzel PT. "Double Agency and the Ethics of Rationing Health Care: A Response to Marcia Angell." *KIEJ* 1993;3(3):287-292; Angell M. "The Doctor as Double Agent." *KIEJ* 1993;3(2):279-286.

[12] Beauchamp TL, Childress JF. *Principles of Biomedical Ethics*, 4th ed. New York: Oxford University Press, 1994.

[13] See Stilling WJ. "Who's in charge: the doctor or the dollar? Assessing the relative liability of third party payers and doctors after Wickline and Wilson." *J Contemp Law* 1992;18:285-307; Hirshfeld EB. "Should Ethical and Legal Standards for Physicians Be Changed to Accommodate New Models for Rationing Health Care?" *U Pa Law Rev* 1992;140:809-846; and Furrow BR. "The Ethics of Cost Containment: Bureaucratic Medicine and the Doctor as Patient-Advocate." *J Law Ethics Public Pol* 1988;3:187-225.

[14] Council on Ethical and Judicial Affairs, American Medical Association. *Code of Medical Ethics*. Chicago, IL,1992; § 2.03.

[15] Hirshfeld, *supra* at 1831-1834; *see also* Furrow, *supra* at 192, note 13 (referencing the Restatement (Second) of Torts and noting that the standard of medical care also takes into account the location or type of community in which a clinician is practicing).

[16] See 61 Am Jur 2d Physicians, Surgeons, and Other Healers §§ 166-168; see also Keeton, et al., *Prosser and Keeton on the Law of Torts*, 5th ed. 1984; § 32.

[17] Hirshfeld, supra at 1838-1839.

[18] Hirshfeld, *supra* at 1838. The legal standard of care is fluid. It is conceivable that this patient-oriented standard of care could be modified in order to accommodate rationing. However, Hirshfeld sets forth compelling arguments against implementing such a change.

[19] There may also be a legal duty to *disclose* to the patient the existence of any roles that conflict significantly with the clinician's role as a health care provider. See generally *Moore v. The Regents of the University of California, et al.*, 51 Cal. 3d 120, 793 P.2d 479, 271 Cal Reptr 146(1990), *cert. denied*, III S.Ct. 1388 (1990).

[20] 5 C.F.R., Part 2635, *Standards of Ethical Conduct for Employees of the Executive Branch*. Under certain circumstances, VA clinicians acting as procurement officials may also be subject to the procurement integrity laws. See generally 41 U.S.C. §§ 401-424. These laws prohibit certain actions involving soliciting, accepting or discussing future employment or business opportunities, soliciting or receiving money, gratuity or anything of value, or disclosing certain proprietary or source selection information. VA employees may seek advice regarding these ethics laws and regulations from the designated agency ethics official. This official can be contacted through the General Counsel's office or, in the field, through the appropriate Regional Counsel's office.

[21] The criminal statutes pertaining to bribery, graft, and conflicts of interest are set forth in 18 U.S.C § 201, *et seq*. These statutes include, for example, a statute pertaining to certain acts affecting employees' personal financial interest. 18 U.S.C. § 208.

[22] Kent DL, Haynor DR, Longstreth WT Jr., et al. "The Clinical Efficacy of Magnetic Resonance Imaging in Neuroimaging." *Ann Intern Med* 1994;120:856-871.

[23] Professional conflicts of interest related to expense and scarcity of medical care are by no means unique to VA. Similar conflicts occur in non-VA health maintenance organizations and managed care networks. See, e.g., "American Medical Association Counsel on Ethical and Judicial Affairs. Ethical Issues in Managed Care." *JAMA* 1995;273:330-335; and Stoeckle JD, Reiser SJ. "The Corporate Organization of Hospital Work: Balancing Professional and Administrative Responsibilities." *Ann Intern Med* 1992;116:407-413. Even in fee-for-service medical settings, patients must use their own discretion and judgment to decide if the marginal benefit accrued to them by an expensive test or treatment justifies the extra cost that may be imposed on them.

[24] Hochia PKO, Tuason VB. "Pharmacy and Therapeutic Committee: Cost-Containment Consideration." *Arch Intern Med* 1992;152:1773-1775. P&T committees do not always save money, however. See Sloan FA, Gordon GS, Cocks DL. "Hospital Drug Formularies and Use of Hospital Services." *Medical Care* 1993;31:851-867.

[25] Wilder BJ, Karas BJ, Penry JK, et al. "Gastrointestinal Tolerance of Divalproex Sodium." *Neurology* 1983;33:808-811.

[26] Hollingsworth JW, Bondy PK. "The Role of Veterans Affairs Hospitals in the Health Care System." *N Engl J Med* 1990; 322:1851-1857.

[27] *Moore v. The Regents of the University of California, et al.*, 51 Cal. 3d 120, 793 P.2d 479, 271 Cal Rptr 146 (1990), *cert. denied*, III S. Ct. 1388 (1990).

[28] The Regents applied for a patent on the cell line, and listed the physician and the researcher as inventors. The court's opinion notes that under established policy [presumably, policy of the University], the regents, the physician, and the researcher would share any royalties or profits arising out of the product. *Moore v. The Regents of the University of California, et al.*, 51 Cal. 3d at 127, 793

P.2d at 481-482, 271 Cal Rptr at 148-149. The court also notes the following:

With the Regents' assistance, Golde [the physician] *negotiated agreements for commercial development of the cell line and products to be derived from it. Under an agreement with Genetics Institute, Golde "became a paid consultant" and "acquired the rights to 75,000 shares of common stock." Genetics Institute also agreed to pay Golde and the Regents "'at least $330,000 over three years, including a pro-rata share of* [Golde's] *salary and fringe benefits, in exchange for … exclusive access to the materials and research performed," on the cell line and products derived from it. On June 4, 1982, Sandoz "was added to the agreement," and compensation payable to Golde and the Regents was increased by $110,000.*

51 Cal. 3d at 127-128, 793 P.2d at 482, 271 Cal Rptr at 149.

29 51 Cal. 3d at 147, 793 P.2d at 496, 271 Cal Rptr at 163.

30 See, e.g., Bernat JL, Beresford HR. "The American Academy of Neurology Code of Professional Conduct." *Neurology* 1993;43:1257-1260.

31 5 C.F.R. Part 2635, *Standards of Ethical Conduct for the Executive Branch.*

32 For a defense of how clinical practice guidelines can both save money and improve the quality of medical care, see Rosoff AJ. "The Role of Clinical Practice Guidelines in Health Care Reform." *Health Matrix* 1995;5:369-396. For a discussion of how practice guidelines impact on professional liability, see Havighurst CC. "Practice Guidelines as Legal Standards Governing Physician Liability." *Law Contemp Prob* 1991;54:87-117.

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14. Ethics Advisory Committees

Purpose of Ethics Advisory Committees (EAC)

The EAC provides a forum in which ethical issues can be discussed with professionals from a wide range of disciplines who possess knowledge in applied ethics. Specifically, the EAC can teach ethics, assist in clinical decision-making, shape health care policies, help to defuse conflicts, disagreements, or uncertainties, foster systematic moral reasoning, enhance communication, and promote the rights of both caregivers and patients.

Through its educational function, consultation service, and proactive influence on policy development, the EAC creates an environment in which both individual and institutional issues are considered in a broad ethical framework. The EAC also contributes to the institution by encouraging continuous self and system evaluation in areas of activity that have an ethical dimension.

In addition to the issues common to all medical care facilities, the EAC in a VHA facility deals with issues that arise from the special nature of the VHA system. The VHA serves a mostly male population. Many VHA patients are from minority groups. Many suffer from substance abuse, poverty, homelessness, and other social dislocations.[1] The limits and special features of care in a system based on entitlement and influenced by political considerations produce unique ethical issues.

VHA health care includes modalities such as spinal cord injury, long term care, and domiciliary facilities, and a very large population of seriously mentally ill patients. As VHA moves toward new coordinated mechanisms of patient care, new issues of distributive justice will arise.

An effective EAC can increase patient, family, and provider satisfaction. By providing a mechanism to foster dispute resolution, the EAC may decrease institutional and individual liability.

Appointment, Composition, and Qualifications of EAC Members

The Medical Center Director should appoint members of the committee. These appointments should be made in consultation with the chair of the EAC and should be guided by the principles discussed below.

In general, qualifications for membership in an EAC reflect two types of expertise. First, there should be representation from the diverse disciplines at the health care facility. The EAC should reflect the professional composition of its institution, with representation from each discipline that plays a significant role in the care of its patient population. Each EAC should also include members who can be identified as patient or community representatives.

The EAC should set policy governing the duration of appointments and turnover of membership. In order to achieve a balance of new and more experienced members, the EAC may consider a structure of a core of experienced and educated members with appointments of long duration and another group with more rapid turnover. This structure permits the development of a large cohort of institutional personnel who have had experience participating in the EAC and provides for a well-functioning, stable committee.

While the EAC should be as broadly representative as is consistent with its effective functioning, appointment of ad hoc consultants to assist the committee in its deliberations concerning individual cases or policies can ensure necessary expertise without making the committee too large for effective functioning.

Members of the EAC should have the necessary background to consider problems in clinical ethics. This background includes a basic awareness of moral theory, key conceptual issues (e.g., consent, autonomy, etc.), common ethical dilemmas, methods of ethical analysis, and relevant health law and regulation. This can be achieved either by selecting persons with such experience and/or knowledge, or by the appointment of persons sufficiently interested and committed to ethics who will acquire such a background. While knowledge and experience with clinical issues is of great importance, commitment and motivation are key qualities for membership in a successful EAC.

Participation in an EAC's activities will enable those without experience and training in ethics to acquire this expertise. On the job training, however, is not sufficient. Each EAC should provide additional training opportunities. They can consist of educational programs, course work, a body of required reading with subsequent discussion, the use of curricula as established by the VHA's Ethics Center or by similar institutions, and, when possible, temporary assignment of individual members to established centers of bioethical teaching.

Functions of EAC

Setting Procedures for its own Operation

Taking into account the special issues and characteristics of its VHA facility, the EAC should set forth its purposes, membership, policies, and procedures in a Medical Center Policy Statement.

Each EAC must establish mechanisms to limit its deliberations to ethical issues and avoid entering into such areas as interpersonal conflicts or issues of employment. Activities of the EAC should not overlap with those of the Institutional Review Board (IRB).

There should be an affirmative procedure to promote patients' knowledge of the EAC.

Educational Role

Education is an essential function of the EAC. It is through this function that a committee can have its strongest effect, creating an ethically aware and knowledgeable institution where people can think clearly, systematically, and constructively about ethical issues. For many committees, case consultation is a primary educational tool. Understanding of ethical issues is fostered through interactions between the EAC and those involved in the care of patients whose ethical problems are brought to the committee. In addition, these cases can provide a broader tool for education if they and the deliberations that they engender are made available throughout the institution.

Many EACs have developed educational programs concerning ethical issues for medical staff, allied health professionals, and other employees. Institutional events such as clinical grand rounds, morbidity and mortality conferences, staff development sessions, ethics rounds, and ethics lunch sessions offer opportunities to further ethics education. Committees may also sponsor conferences and workshops.

Ethics education should be targeted to patients, their families, clinical and managerial professionals, and the community at large. This educational process promotes understanding of ethical problems and awareness of an institution's desire to respond in an ethical manner. For instance, medical centers have provided information to patients and families about advance directives. EAC's may also consider providing educational activities to the community beyond its own institution. Programs concerning issues in medical ethics can be aimed at patients, their families, and the community.

Case Consultation

The EAC serves as a consulting group to patients, families, and the health care team when problems based on issues of medical ethics or patients' rights arise. Any of the persons involved in the problem, including all members of the staff, patients, and/or those who wish to speak on patients' behalf should be able to initiate involvement of the EAC.

The EAC has the responsibility to facilitate discussion about the ethical issues raised by the patient, family, health care team, or other advocates. The EAC gathers and assesses data, clarifies and identifies the ethical challenges, applies principles of ethics to the ethical issues raised, clarifies the rights of the parties involved, and makes recommendations regarding steps that the parties can take to develop a solution. Frequently, resolution will emerge simply by providing a forum in which each party can state one's views to an impartial but sympathetic group.

Each EAC should provide and define a structure for its consultative function that is effective and appropriate for its institution. For instance, many committees designate a small subcommittee that responds promptly to requests for consultation. This subcommittee meets with the health care team (and the patient and/or family, as appropriate), reviews the clinical record, and offers its recommendations. All recommendations should be available for review by the full committee and noted in its minutes. The subcommittee may sometimes offer recommendations directly, when, for example, it addresses issues previously resolved by the full committee.

The EAC should note its findings and recommendations in the patient's chart. As is true for other consultative services, these recommendations are advisory, and responsibility for the ultimate decisions rests with the attending clinicians. There may be rare instances, however, when, after the consultative process, the EAC members think that important rights of one or more of the parties are being seriously compromised. In such instances, the EAC shall, after making an effort to resolve the issues directly, report its findings and concerns to the Chief of the involved services. The Chief of Staff may also need to be consulted when his or her authority is necessary to insure an equitable solution.

Policy Development and Review Role

Broad administrative and clinical decisions within a medical center frequently have important bioethical dimensions. The EAC should be involved in this decision-making. For example, an EAC can give an

ethically informed analysis of what counts as equitable distribution of limited resources. The major institutional decision-making bodies, such as the Clinical Executive Board, should be prepared to turn to the EAC for consultation when they face issues with an important ethical component, such as those arising from managed health care.

The EAC should play a primary consultative role when the institution develops policies that focus on the rights of patients. These would include policies governing Do Not Resuscitate (DNR), advance directives, informed consent, palliative care, and other end-of-life planning.

The EAC's ability to provide ethical direction in institutional policy decision-making is potentially its most important role. For the EAC to fulfill this responsibility, it must restructure its own activities, and the institution must similarly reorganize its policy development and review process, to permit ongoing input concerning ethical aspects of the issues under consideration.

As is the case for clinical consultations by the EAC, the role of the committee in the development of institutional policies is advisory. At the institutional or national level, VHA may in the future develop policies that mandate the participation of EACs in special circumstances. While the advice and participation of the EAC can provide a crucial procedural safeguard, giving final authority or responsibility to an EAC should be avoided.

Role in Furthering Research and Evaluation

An EAC should play a role in fostering research in areas of ethics. This responsibility can be carried out by having the committee, a subcommittee, or individual members initiate research projects that arise from issues that the committee has faced.

Each local committee should consider regular evaluation of its activities. Evaluation can be a time consuming process, yet is a necessary step to improve the committee's understanding of its needs and impact. Methods can vary, from special meetings in which the committee's role, membership, and procedures are discussed, to the use

of a self-assessment survey. In addition to self-assessment by EAC members, the committee should consider performing occasional institution-wide surveys seeking information about effectiveness of the committee. The committee can use the information to see if there are previously unrealized needs, such as broader education programs or an improved consultation process.[2]

Record keeping by EACs should include essential data concerning consultations, such as persons in attendance, ethical issues discussed, and recommendations made. Committees can then retrospectively review their activities. EACs should regularly review their membership, including the degree of participation, to ascertain if they are sufficiently broadly based and representative.

Studies initiated or carried out by members of the EAC can have an important function. Quality assurance reviews of advance directive procedures, for instance, may focus on such questions as whether proxies are being asked for consent for DNR orders when the patient is not competent to make his or her own decisions, or whether such orders, rescinded for surgery, are being appropriately reinstated.

JCAHO Standards and VHA Ethics Advisory Committees

The Joint Commission on Accreditation of Health Organizations (JCAHO) has established standards entitled “Patient Rights and Organizational Ethics” that place many responsibilities on EACs. While the standards do not require medical centers to have an EAC, a mechanism to ensure that there is “a functioning process to address ethical issues” is required. In VHA, EACs are expected to satisfy the requirement.

JCAHO standards focus on issues such as consent of patients and surrogates, advance directives, withholding resuscitation, and forgoing or withdrawing life-sustaining treatment. The standards define a need for medical center policy and involvement of patients or surrogates in decision-making. The JCAHO standards move the EAC beyond policy

and consultative activities to the need of every medical center to "establish and implement a code of ethical behavior." This JCAHO requirement enlarges the traditional role of an EAC to foster "an environment of ethical practice." The EAC is expected to provide to the JCAHO examiners evidence that the facility has achieved this goal. This process can also serve as a useful method for fostering a general review of the EAC program.[3]

Role in Ensuring That Institutions Maintain a Process for Monitoring the Application of Ethical Principles

The EAC should serve as a resource to the quality management structure within the VHA facility to ensure that the JCAHO's patient rights and organizational ethics standards are maintained. These include but are not limited to:

- description of the process utilized to address ethical issues that arise in patient care,
- procedures for obtaining informed consent,
- procedures addressing the role of surrogate decision-makers,
- the formulation of advance directives,
- decisions to withhold resuscitation,
- decisions to withhold or withdraw life-sustaining treatment,
- guidelines for organ procurement, and
- use of patient restraints.

The various standards provide a means of evaluating that the institution has developed a functioning process to address ethical issues. At most VHA healthcare facilities, the EAC will play a key role in verifying the ethical care of patients.

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About the VHA Ethics Center

The Veterans Health Administration (VHA) Ethics Center is the system's primary office for analysis of ethical issues in health care. The Center consults on particular issues as they present both to VHA Headquarters and to clinical sites. Center bioethicists provide education and training to front-line clinicians, managers and administrators, and develop, teach and interpret ethics-related policies. The Center supports a national network of Ethics Advisory Committees (EACs) and sponsors an annual Ethics Intensive Training Course for EAC members.

Most pertinent to this volume, the Ethics Center oversees the VHA Bioethics Committee. The Committee is composed of 25 physicians, nurses, social workers, chaplains, managers, administrators, veterans advocates, and ethicists from throughout the veterans health care system. One of the Committee's responsibilities is to research and publish reports on particular ethical issues in health care. The reports are topical: each one summarizes relevant historical perspectives, reviews current controversies, clarifies matters of importance to VHA's mission, and outlines pragmatic applications of guiding principles. The Bioethics Committee welcomes this opportunity to combine these 14 reports under one cover in order to more effectively share its deliberations both within VHA and beyond.